

Regulatory Impact Analysis

Amendments to 15A NCAC 13A .0111 –
Addition of the Federal Management Standards for Hazardous Waste
Pharmaceuticals Rule Provisions

NCDEQ
Division of Waste Management
Hazardous Waste Section

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General Information

Commission:	Environmental Management Commission
Agency:	Department of Environmental Quality (DEQ), Division of Waste Management (DWM), Hazardous Waste Section
Title:	Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities
Citation:	15A NCAC 13A .0111
Description of the Proposed Rules:	The Hazardous Waste Management Rules - 15A NCAC 13A .0111 are proposed for amendment to include the provisions of the federal Management Standards for Hazardous Waste Pharmaceuticals Rule.
Agency Contact:	Jenny Patterson, Environmental Program Consultant Division of Waste Management, Hazardous Waste Section Jenny.Patterson@ncdenr.gov 336-767-0031
Rulemaking Authority:	N.C.G.S. 130A-294
Statement of Necessity:	The Division of Waste Management is proposing the amendments due to a change in a federal regulation: 84 Federal Register (FR) 5816 (February 22, 2019) "Management Standards for Hazardous Waste Pharmaceuticals Rule."
Fiscal Impact Summary:	State Government: Yes Local Government: Yes Federal Government: Yes Private Entities: (Businesses – Yes, Homeowners – No) Substantial Impact: No

Rule Summary

It is the responsibility of the Division of Waste Management, Hazardous Waste Section to regulate how hazardous waste is managed within the state under the statutory authority of N.C.G.S. Chapter 130A-294. State rules governing hazardous waste management are found in Title 15A, Subchapter 13A of the North Carolina Administrative Code (NCAC).

The Hazardous Waste Management Rules, 15A NCAC 13A .0111, are proposed for amendment due to a change in a federal regulation.

On February 22, 2019, the United States Environmental Protection Agency (EPA) promulgated a final rule concerning the regulation of hazardous waste pharmaceuticals, in 84 Federal Register (FR) 5816 (February 22, 2019) ("Management Standards for Hazardous Waste Pharmaceuticals Rule")¹. The effective date of this rule on the federal level is August 21, 2019.

This federal rule creates a new 40 Code of Federal Regulations (CFR) part 266 subpart P ("subpart P") for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors in lieu of the hazardous waste generator regulations in 40 CFR part 262. This new subpart establishes definitions and management standards for potentially creditable (unused, returnable), non-creditable (used, not-returnable) and evaluated hazardous waste pharmaceuticals. The new subpart prohibits the disposal of hazardous waste pharmaceuticals down the drain and eliminates the dual regulation of Resource Conservation and Recovery Act (RCRA) hazardous waste pharmaceuticals that are also Drug Enforcement Administration (DEA) controlled substances by finalizing a conditional exemption. The new subpart also maintains the household hazardous waste exemption for pharmaceuticals collected during pharmaceutical take-back programs and events, while ensuring their proper disposal and codifies EPA's prior policy on the regulatory status of nonprescription pharmaceuticals going through reverse logistics.

The prohibition of sewerage hazardous waste pharmaceuticals (40 CFR 266.505) is finalized under Hazardous and Solid Waste Amendments (HSWA) authority in section 3018 of RCRA. The amendments promulgated under the authority of HSWA are applicable on the effective date of the final rule in all states. The prohibition of sewerage hazardous waste pharmaceuticals was effective nationwide on August 21, 2019 and administered and enforced by EPA until authorized states adopt the provision. All other federal provisions of the Hazardous Waste Pharmaceuticals Rule are not effective until after state adoption.

Provisions of the Management Standards for Hazardous Waste Pharmaceuticals Rule are required to be adopted to maintain state authorization. The preamble of the rule (84 FR 5936; February 22, 2019) states the following on the requirement of adoption: "While some provisions of part 266 subpart P are considered less stringent than the current federal standards, other provisions of the final rule are considered more stringent than the current federal standards. Taken as a whole, we consider the entire new subpart P under 40 CFR part 266 entitled 'Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities'...to

¹ The Management Standards for Hazardous Waste Pharmaceuticals Rule (84 FR 5816; February 22, 2019) can be found at the following website link: <https://www.govinfo.gov/content/pkg/FR-2019-02-22/pdf/2019-01298.pdf>

be more stringent than the current federal standards. Therefore, authorized states will be required to modify their programs to adopt these revisions."

The proposed amendments that incorporate the provisions of the required federal Management Standards for Hazardous Waste Pharmaceuticals Rule with no substantive amendments or exceptions, are found in 15A NCAC 13A .0111 (see Appendix J for the proposed rule text). The provisions of the Management Standards for Hazardous Waste Pharmaceuticals Rule (with the exception of the sewer prohibition which was effective nationwide on August 21, 2019) are anticipated to be effective in North Carolina on July 1, 2020.

Purpose/Necessity

The purpose of this document is to conduct an evaluation of the costs and benefits associated with amendments of 15A NCAC 13A .0111. The amendments made to 15A NCAC 13A .0111 are necessary due to recent changes to applicable federal regulations and to also maintain federally delegated program authority.

The purpose of the Management Standards for Hazardous Waste Pharmaceuticals Rule is to create streamlined standards for handling hazardous waste pharmaceuticals to better fit the operations of the healthcare sector while protecting human health and the environment.

One goal of the federal rule is to reduce the amount of pharmaceuticals that are disposed of down the drain. Many healthcare facilities used drain disposal (e.g., flushing) as a routine disposal method for pharmaceutical wastes, including those that are hazardous waste. Prior to this federal rule, sewer disposal was an allowable RCRA disposal method for hazardous waste pharmaceuticals. Reducing intentional sewer disposal is one way to help reduce the environmental loading of hazardous waste pharmaceuticals that enter the publicly owned wastewater treatment system and subsequently the surface water. The federal rule will make drinking and surface water safer and healthier by reducing the amount of hazardous waste pharmaceuticals entering surface waters. An estimated 32 ton reduction of hazardous waste pharmaceuticals per year in North Carolina waterways is the result of prohibiting all facilities subject to the rule in the North Carolina from sewerage hazardous waste pharmaceuticals.

In addition to protecting human health and the environment, this federal rule will improve compliance at healthcare facilities and reverse distributors by responding to stakeholder concerns about the difficulty and complication of implementing the RCRA hazardous waste regulations for hazardous waste pharmaceuticals generated at healthcare facilities. Under hazardous waste regulatory requirements, a small portion of pharmaceuticals are regulated as hazardous wastes when disposed. In the healthcare setting, a wide variety of pharmaceuticals are used, and hazardous waste pharmaceuticals are generated in relatively small quantities by a large number of different employees across the facility. This situation differs from a typical manufacturing facility where fewer employees in a few locations generate comparatively much larger volumes of a smaller range of hazardous wastes. The primary focus of healthcare personnel is to provide patient care. The Management Standards for Hazardous Waste Pharmaceuticals Rule facilitates compliance among healthcare facilities by creating a tailored, sector-specific regulatory

framework for managing hazardous waste pharmaceuticals at healthcare facilities and reverse distributors. The rule clarifies the regulatory status for the management of both used and unused and/or expired pharmaceuticals for healthcare facilities and reverse distributors which reduces the confusion about proper management and increases compliance. The Management Standards for Hazardous Waste Pharmaceuticals Rule allows healthcare personnel to focus on healthcare while still ensuring that hazardous waste is directed to proper management.

The federal rule also addresses the overlap between RCRA hazardous waste regulations and the DEA regulations for controlled substances. Stakeholders indicated that hazardous waste pharmaceuticals that are also controlled substances are stringently regulated and therefore are expensive to manage and dispose of in accordance with both sets of regulations. In addition, stakeholders have indicated that the RCRA hazardous waste pharmaceuticals that are also DEA controlled substances are most likely to be sewer disposed to avoid the costs of compliant incineration. This federal rule eliminates the regulatory overlap between hazardous waste pharmaceuticals that are both DEA and RCRA regulated which reduces the unnecessary regulatory and monetary burden for healthcare facilities. The federal rule helps reduce intentional sewer disposal of pharmaceuticals thereby improving compliance for the healthcare facility while improving the health and safety of the state's waterways by reducing hazardous waste pharmaceuticals discharged through publicly owned treatment works.

Fiscal Impact Summary

The proposed amendments to the Hazardous Waste Management Rules 15A NCAC 13A .0111 to incorporate the federal provisions of the Management Standards for Hazardous Waste Pharmaceuticals Rule will result in an initial net economic cost to the private sector and federal and local government until one year after the amendments are effective (2021), then these entities will realize a net benefit. State government will experience a net cost due to the amendments. Table 1, on page 8, summarizes the costs, benefits, net impact and net present value of the impact over 11 years to the different facility types (private and federal, state, and local government). Table 2, on page 9, summarizes the net impact to the facility types. The 11-year net present value of the impact to all parties involved is \$349,955 in 2019 dollars, using a 7% discount rate. Since the aggregate financial impact of the proposed amendments on all persons affected does not exceed \$1 million per year, the rule amendments are not considered to create a substantial impact.

Some of the benefits that will accompany the adoption of the Management Standards for Hazardous Waste Pharmaceuticals Rule are difficult to quantify (see the *Fiscal Impact Analysis, Summary of Unmonetized Benefits* section for more information on unquantified benefits). Increased protection to human health and the environment will be a result of the implementation of the sewer prohibition by reducing the amount of hazardous waste pharmaceuticals that enter the publicly owned wastewater treatment system and subsequently the surface water. An estimated 32 tons of hazardous waste pharmaceuticals a year will be kept from entering waterways in North Carolina by prohibiting all facilities subject to the rule from sewerage them.

Since some benefits are not quantified, some of the tables in this analysis appear, at times, to have costs that are not offset by benefits. The quantified costs of the proposed rules can be compared

against the expected, but unquantified, benefits in the form of hazardous waste management cost-savings and improved surface and drinking water protections.

The sewer prohibition of the Management Standards for Hazardous Waste Pharmaceuticals Rule creates the most cost impact over time (see Appendix D for more information). While the DEA exemption creates the most benefit impact over time, there is a period of time (11 months) between when the sewer prohibition was effective (August 2019) and when the DEA exemption is effective (July 2020) that healthcare facilities must manage the hazardous waste pharmaceuticals that are DEA controlled substances through incineration and meet RCRA hazardous waste requirements. During these 11 months, there are costs associated with the management and disposal of the hazardous waste pharmaceuticals that are also DEA controlled substances. A one-time training cost also adds to the cost impact to all facility types on the first year the amendments are effective.

The most impacted facility type are the private sector healthcare facilities and reverse distributors. On the first year, the Management Standards for Hazardous Waste Pharmaceuticals Rule is anticipated to be effective (2020), private healthcare facilities have a \$197,204 net cost associated with the proposed amendments. After the first year the amendments are effective, the private sector realizes a net benefit. Private sector healthcare facilities and reverse distributors make up 97.4% of the total number of healthcare facility and reverse distributor hazardous waste generators in North Carolina -- which accounts for the higher impact to this facility type.

State government healthcare facilities make up only 1.2% of the total healthcare facilities in North Carolina. However, the impacts to state government include a net loss to state government healthcare and to the Hazardous Waste Section (a state government entity) with the Hazardous Waste Section having a higher cost impact due to a loss in hazardous waste generator fees received from healthcare facilities that can downgrade their hazardous waste generation category due to the rule amendments (see Appendix B for more information). The net cost/benefits for state government are further refined in Table 3, on page 9, to reflect the net cost/benefit for the state government hazardous waste generators versus the Hazardous Waste Section.

Even with the economic impact that is experienced by the different facility types, the North Carolina Hazardous Waste Management Program's rules must be at least as stringent as the federal rules in order for North Carolina to maintain State Authorization with EPA. It is mandatory for the state to adopt the provisions of the federal Management Standards for Hazardous Waste Pharmaceuticals Rule. Maintaining State Authorization of the Hazardous Waste Management Program is beneficial to the state, the regulated entities, and the public. This allows for continued opportunities to maintain relationships and lines of communication between the regulators, the regulated entities, other local regulatory agencies and the public; maintains the ability and opportunities to engage with stakeholders and work through issues on a local level; improves the level of compliance by having a physical presence; and reduces response time to emergencies and requests for technical assistance compared to federal implementation.

Table 1

Estimated Impacts of Proposed Amendments to 15A NCAC 13A .0111											
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
BENEFITS*											
Private Sector	\$0	\$104,516	\$140,011	\$147,725	\$140,675	\$148,713	\$141,417	\$149,785	\$141,999	\$151,051	\$142,959
Federal Government	\$0	\$4,614	\$9,228	\$9,229	\$9,229	\$9,230	\$9,231	\$9,232	\$9,232	\$9,233	\$9,234
State Government	\$0	\$4,622	\$9,245	\$9,246	\$9,247	\$9,247	\$9,248	\$9,249	\$9,249	\$9,250	\$9,251
Local Government	\$0	\$20,765	\$27,769	\$29,309	\$62,042	\$29,472	\$28,019	\$29,646	\$28,139	\$29,876	\$28,330
Total Benefits	\$0	\$134,518	\$186,253	\$195,508	\$221,192	\$196,662	\$187,914	\$197,912	\$188,620	\$199,411	\$189,774
COSTS											
Private Sector	\$58,047	\$301,720	\$38,695	\$38,798	\$68,584	\$33,957	\$33,957	\$33,957	\$33,957	\$33,957	\$33,957
Federal Government	\$6,617	\$24,704	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554
State Government	\$12,376	\$69,949	\$36,166	\$36,326	\$38,390	\$32,300	\$29,780	\$29,780	\$29,780	\$29,780	\$29,780
Local Government	\$9,498	\$22,113	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764
Total Costs	\$86,537	\$418,486	\$83,179	\$83,442	\$115,292	\$74,575	\$72,055	\$72,055	\$72,055	\$72,055	\$72,055
NET IMPACT	-\$86,537	-\$283,968	\$103,074	\$112,067	\$105,900	\$122,087	\$115,859	\$125,857	\$116,565	\$127,356	\$117,719
The 11-year NPV of Impact is \$349,955.											
* Not all expected benefits are captured in this table. This table reflects only monetized impacts. Some benefits are nonmonetized and further discussed in the Fiscal Impact Analysis, Summary of Unmonetized Benefits section of this document.											

Table 2

Estimated Impacts of Proposed Amendments to 15A NCAC 13A .0111											
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Private Sector Net Cost/Benefit	-\$58,047	-\$197,203	\$101,316	\$108,927	\$72,091	\$114,756	\$107,460	\$115,828	\$108,042	\$117,094	\$109,002
Federal Government Net Cost/Benefit	-\$6,617	-\$20,090	\$2,674	\$2,675	\$2,675	\$2,676	\$2,677	\$2,678	\$2,678	\$2,679	\$2,680
State Government Net Cost/Benefit	-\$12,376	-\$65,327	-\$26,921	-\$27,080	-\$29,143	-\$23,053	-\$20,532	-\$20,531	-\$20,531	-\$20,530	-\$20,529
Local Government Net Cost/Benefit	-\$9,498	-\$1,348	\$26,005	\$27,545	\$60,278	\$27,708	\$26,255	\$27,882	\$26,375	\$28,112	\$26,566
Total Net Impact	-\$86,537	-\$283,968	\$103,074	\$112,067	\$105,900	\$122,087	\$115,859	\$125,857	\$116,565	\$127,356	\$117,719

Table 3

Impact to State Government: Healthcare Facilities vs. Hazardous Waste Section											
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
State Government Healthcare Facility Net Cost/Benefit	-\$7,111	-\$27,919	\$1,469	\$1,469	\$1,517	\$1,517	\$1,518	\$1,519	\$1,519	\$1,520	\$1,521
State Government Hazardous Waste Section Net Cost/Benefit	-\$5,265	-\$37,408	-\$28,390	-\$28,549	-\$30,660	-\$24,570	-\$22,050	-\$22,050	-\$22,050	-\$22,050	-\$22,050
Total Net Impact	-\$12,376	-\$65,327	-\$26,921	-\$27,080	-\$29,143	-\$23,053	-\$20,532	-\$20,531	-\$20,531	-\$20,530	-\$20,529

Certificate of Federal Requirement

In accordance with requirements outlined in N.C.G.S. 150B-19.1(g), the Division of Waste Management is proposing changes to the Hazardous Waste Management Rules - 15A NCAC 13A.0111. These changes will make the State Hazardous Waste Program equivalent to, consistent with, and no less stringent than the federal RCRA program, by incorporating required federal changes to 40 CFR 266. The EPA has authorized North Carolina to operate the State Hazardous Waste Program in lieu of the federal program under the Resource Conservation and Recovery Act ("RCRA"), 42 U.S.C. §§ 6901 to 6992k. Because the State Hazardous Waste Program is federally delegated, EPA continues to exercise oversight—including the ability to revoke program authorization—to ensure consistency with RCRA. Specifically, the State Hazardous Waste Program must remain equivalent to, consistent with, and no less stringent than the Federal program. RCRA § 3006(b), 42 U.S.C. § 6926(b); 40 C.F.R. § 271.4. The Act instructs the Department to "cooperate . . . with . . . the federal government . . . in the formulation and carrying out of a solid waste management program," including a program for the management of hazardous waste "designed to protect the public health, safety, and welfare; [and to] preserve the environment." N.C.G.S. 130A-294(a)(2) and (b). The Act mandates the adoption of rules to implement that program. N.C.G.S. 130A-294(b).

When new, more stringent federal requirements are promulgated, North Carolina is obligated to enact equivalent authorities within one year of the adoption of each new, more stringent rule (two years if legislation must be enacted).

The EPA considers the provisions of this rule (taken as a whole) to be more stringent than the current standards and North Carolina must adopt the provisions of the federal "Management Standards for Hazardous Waste Pharmaceuticals Rule" that was promulgated on February 22, 2019 (84 FR 5816) to maintain state authorization. The proposed changes to 15A NCAC 13A .0111(g) and (h) will make the State Hazardous Waste Program equivalent to, consistent with, and no less stringent than the federal RCRA program, by incorporating federal changes.

Fiscal Impact Analysis

A review of all proposed amendments to the Hazardous Waste Management Rules - 15A NCAC 13A .0111 was conducted to determine whether a cost and/or benefit was created by each provision. A summary of the proposed amendments is in the Fiscal Impact Analysis – Summary of Proposed Amendments section on page 15. Appendix I contains detailed summaries of costs and benefits broken down for each facility type (private sector and federal, state and local government) by rule amendment along with the net impact and net present value of the 11-year impact for each individual facility type. The development of the costs/benefits associated with proposed amendments is in Appendix B through H.

Summary of Affected Parties

The Management Standards for Hazardous Waste Pharmaceuticals Rule applies to all healthcare facilities that generate, accumulate, or otherwise handle hazardous waste pharmaceuticals and are small quantity generators or large quantity generators when total volume of hazardous waste (both pharmaceutical and non-pharmaceutical hazardous waste) are calculated. All reverse distributors (facilities that receive and accumulate prescription pharmaceuticals for the purpose of facilitating manufacturer credit) engaged in the management of prescription hazardous waste pharmaceuticals regardless of their hazardous waste generator category, are required to manage their hazardous waste pharmaceuticals under 40 CFR subpart P, instead of the hazardous waste generator regulations in 40 CFR part 262. Additionally, healthcare facilities that are very small quantity generators must comply with the sewer prohibition for their hazardous waste pharmaceuticals under 40 CFR part 266 subpart P and have the option of complying with the entire subpart P in lieu of operating under the conditional exemption of 40 CFR 262.14 (which has been incorporated by reference at 15A NCAC 13A .0107(a) and are the current requirements by which very small quantity generators manage hazardous waste pharmaceuticals).

The Management Standards for Hazardous Waste Pharmaceuticals Rule defines healthcare facilities as any person that is lawfully authorized to:

- (1) Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or
- (2) Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies, long term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

Because not all healthcare facilities and pharmaceutical distributors are hazardous waste generators, not all of these facilities will be affected by the Management Standards for Hazardous Waste Pharmaceuticals Rule. With the exception of the sewer prohibition, only the healthcare facilities that generate large and small quantity amounts of hazardous waste will be subject to the requirements of the rule.

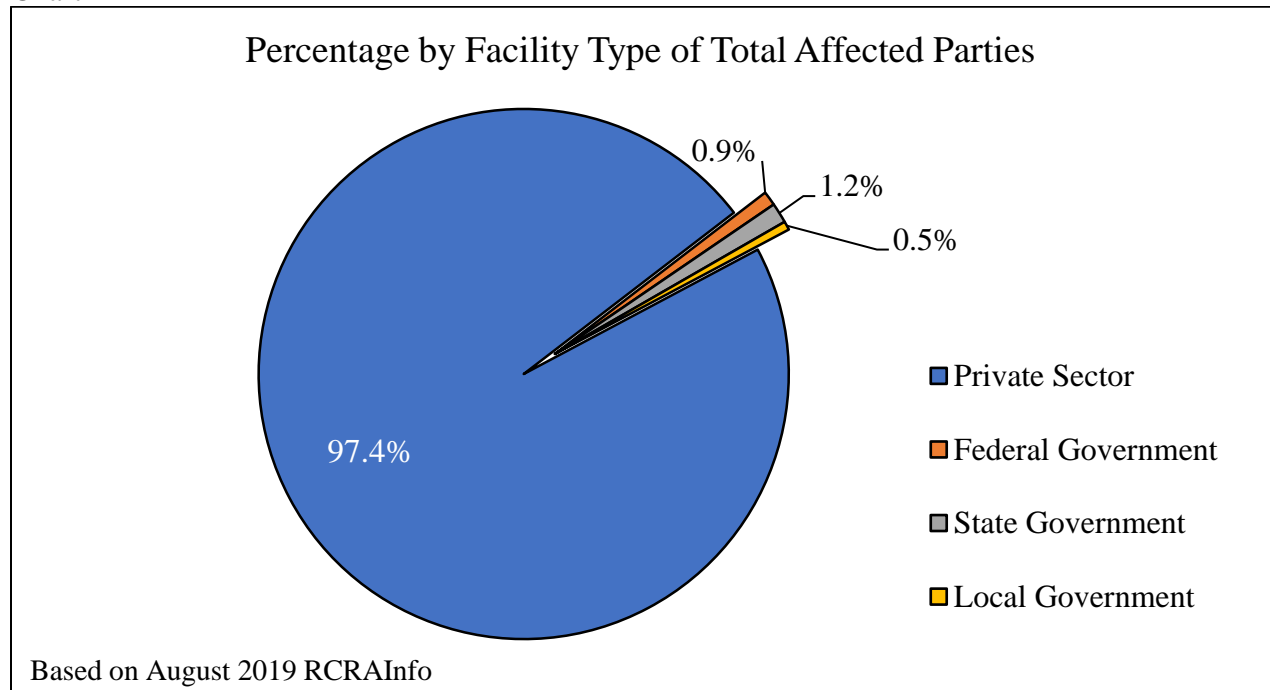
Hazardous waste generators in North Carolina are divided into three categories: very small quantity generators, small quantity generators and large quantity generators. The different categories are based on the volume of hazardous waste generated in a calendar month and the amount of hazardous waste accumulated on site at any time. The regulatory requirements increase with the increased amount of hazardous waste that is generated in a calendar month and/or accumulated on site at any time (i.e. the large quantity generator has the most requirements of the three hazardous waste generator categories).

Large quantity generators and small quantity hazardous waste generators are required to notify with the Hazardous Waste Section of their hazardous waste activity using EPA's database called RCRAInfo. Very small quantity generators are not required to notify of their hazardous waste activity with the Hazardous Waste Section.

The data from the notifications submitted to the Hazardous Waste Section is entered into a national EPA database, "RCRAInfo." The Hazardous Waste Section is able to query and track hazardous waste generator categories and other generator information by using the database. Even though very small quantity generators are not required to notify of their activity, some facilities voluntarily submit the notification. Additionally, some very small quantity generators had previously operated at a higher category (small quantity or large quantity) before renotifying as a very small quantity generator so the information is maintained in the RCRAInfo database.

The hazardous waste generators (of all categories) that are affected by the Management Standards for Hazardous Waste Pharmaceuticals Rule are comprised mostly of private sector businesses and industry. Based on August 2019 data from the RCRAInfo database, private sector hazardous waste generator healthcare and reverse distributors make up 97.4% of the total number of affected parties. The percentage by type of the total number of hazardous waste generators for August 2019 is shown in Chart 1, below.

Chart 1



Hazardous waste generators also include federal, state and local government entities. The federal government healthcare facilities in North Carolina operating as hazardous waste generators include entities such as Veterans Administration hospitals and healthcare clinics, military bases, prison complexes, and Coast Guard stations. State government healthcare entities in North Carolina operating as hazardous waste generators include colleges and universities with hospitals or

healthcare clinics, veterinary hospitals and clinics, and North Carolina Department of Health and Human Services facilities. Local government facilities include city and county facilities such as health departments, school nurses' offices and hospitals. Table 4, below, provides a summary (as of August 2019) of the number of different types of healthcare facilities and reverse distributors that are hazardous waste generators (private, local government, state government, and federal government) and the number in each category (very small quantity generator, small quantity generator and large quantity generator).

Table 4

Healthcare Facilities and Reverse Distributors in North Carolina by Hazardous Waste Generator Category Entered in RCRAInfo Database as of August 2019						
Category of Hazardous Waste Generator	Number of Healthcare Facility/Reverse Distributor Hazardous Waste Generators – Private Sector	Number of Healthcare Facility Hazardous Waste Generators – Federal Government	Number of Healthcare Facility Hazardous Waste Generators – State Government	Number of Healthcare Facility Hazardous Waste Generators – Local Government	Total Number of Healthcare Facility/Reverse Distributor Hazardous Waste Generators in North Carolina	Total Number of Hazardous Waste Generators in North Carolina
Large Quantity Generator	20	2	2	3	27	418
Small Quantity Generator	101	1	3	0	105	1,811
Very Small Quantity Generator	432	2	2	0	436*	5,219*
Total	553	5	7	3	568	7,448

* Number represents the very small quantity generators that have notified of their hazardous waste activity. The actual number of very small quantity generators in NC will be higher.

Since very small quantity generators are not required to notify the Hazardous Waste Section of hazardous waste activity, the numbers used in determining the current number is the number of known very small generators that have notified at this status. The actual number of very small quantity generators in North Carolina is likely higher.

The actual number of very small quantity generators is highly uncertain since these facilities are not required to notify of their hazardous waste generation activity. There is not an accurate way to estimate the actual number of this category of hazardous waste generators. The EPA Regulatory Impact Analysis² estimates the size of the very small quantity generator universe, through extrapolating from the limited data collected from nine states and calculated the ratio of: (1) very small quantity generators to small quantity generators and (2) very small quantity generators to large quantity generators. The ratios calculated (7.3 and 23.5 ratio of very small quantity generator to small quantity generator and large quantity generators respectively) are multiplied by the

² EPA's Regulatory Impact Analysis, Page 22

number of small quantity generators and large quantity generators in the state to estimate low-end and high-end estimates of the number of very small quantity generators.

If this ratio is used along with the current number of health care facilities and reverse distributors that are small quantity generators (105) and large quantity generators (27) in North Carolina, the estimated number of health care facilities and reverse distributors that are actually currently very small quantity generators in North Carolina would be between 635 and 767. The number of facilities that have reported their status voluntarily or have previously operated at another hazardous waste generation status before downgrading to very small quantity generator in the RCRAInfo database is 432.

Based on the EPA's Regulatory Impact Analysis, there is a large discrepancy between the extrapolated number of very small quantity generators and the number that have voluntarily notified of their hazardous waste generation activity in North Carolina. The only proposed regulatory amendment with associated costs and benefits that depends on the total number of very small quantity generators is the provision that prohibits the sewerage of hazardous waste pharmaceuticals. For purposes of this document, the known number of very small quantity generators (432) will be used.

There are five known reverse distributors in North Carolina. The reverse distributors are all private sector facilities. The reverse distributors were identified through Hazardous Waste Section knowledge of hazardous waste generators, the hazardous waste biennial report, and by matching facility names with the names of known reverse distributors identified by the U.S. Drug Enforcement Administration (DEA). The reverse distributors currently operate as large quantity generators of hazardous waste and will continue to operate as large quantity generators of hazardous waste after the provisions of the Management Standards for Hazardous Waste Pharmaceuticals Rule is effective in North Carolina.

The proposed rule amendments do not affect waste that is generated by homeowners (household hazardous waste is exempt from regulation as a hazardous waste), so there is expected to be no economic impact on private individuals. Private sector businesses and industry that do not generate hazardous waste are also not affected by these proposed rule amendments.

Economic impact will also be realized by the Hazardous Waste Section (a state government agency). No other federal, state, and local government agencies located in North Carolina regulate hazardous waste and therefore have no economic impact as far as enforcing the rules.

After this rule is effective in North Carolina, it is anticipated that some of the healthcare facilities that are currently operating as large quantity generators of hazardous waste will be able to downgrade their hazardous waste generator category to small quantity generator. Based on Hazardous Waste Section knowledge of the healthcare facilities currently operating as a large quantity generator of hazardous waste, 15 private sector and 3 local government healthcare facilities will be able to renotify as a small quantity generator once the rule is effective in North Carolina. The healthcare facilities that will remain a large quantity generator (2 federal government and 2 state government facilities) will remain a large quantity generator due to the amount of non-pharmaceutical hazardous waste generated at the facility. The costs and benefits associated with

the ability to reduce hazardous waste generator category because of this rule are summarized in Appendix B.

Summary of Proposed Amendments

15A NCAC 13A .0111 Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities – Part 266

This state rule currently incorporates by reference parts of federal regulation 40 CFR 266 and provides state specific information on the management of specific hazardous wastes and specific types of hazardous waste management facilities including recyclable materials that are used in a manner constituting disposal, recyclable materials utilized for precious metal recovery, spent lead acid batteries being reclaimed, hazardous waste burned in boilers and industrial furnaces, and low level mixed waste managed under a conditional exemption.

15A NCAC 13A .0111(g) is proposed for amendment by incorporating by reference provisions from the federal Management Standards for Hazardous Waste Pharmaceuticals Rule -- Specifically 40 CFR 266.500 through 266.510 is collectively "subpart P." Below is a summary of the federal provisions that are proposed to be incorporated by reference at 15A NCAC 13A .0111(g). The development of the costs associated with the proposed amendments can be found in Appendix B through H.

- 40 CFR 266.500 Definitions: This provision establishes new definitions used in subpart P. There is no cost/benefit directly associated with this amendment of the state rules to incorporate the definitions in 40 CFR 266.500 by reference. Indirectly, there is a cost associated with providing training for the Hazardous Waste Section and regulated entities, but these costs are addressed with the costs associated with other provisions in subpart P that utilize these new definitions. The development of the costs associated with additional training is in Appendix C.
- 40 CFR 266.501 Applicability: This provision establishes which facilities must comply with the provisions of subpart P and to which pharmaceuticals the standards are applicable. There is no cost/benefit associated with this amendment of the state rules to incorporate the applicability terms in 40 CFR 266.501 by reference. The specifications described in this federal provision assembled the cohort of affected parties used in this Regulatory Impact Analysis.
- 40 CFR 266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals: This provision provides the management requirements for used, partially used, or expired (beyond one year) prescription hazardous waste pharmaceuticals used in patient care and discarded by healthcare facilities. This type of hazardous waste pharmaceutical has no reasonable expectation to receive a manufacturer credit and is referred to as "non-creditable hazardous waste pharmaceuticals." The management requirements include notifying that the facility is operating under subpart P; containerizing the waste in containers that are closed, labeled, structurally sound, compatible with the

contents, and lacks evidence of leaks and spills; ensuring the waste is not accumulated on site for more than one year; manifesting the waste to a permitted or interim status hazardous waste treatment, storage, and disposal facility. The development of the costs associated with this provision are in Appendix C.

- 40 CFR 266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals: This provision provides the management requirements for prescription hazardous waste pharmaceuticals that are expired (less than one year), recalled, and otherwise unused pharmaceuticals that have a reasonable potential to receive manufacturer credit -- known as "potentially creditable hazardous waste pharmaceuticals." Potentially creditable hazardous waste pharmaceuticals may be sent to reverse distributors for evaluation for manufacturer credit. The management standards associated with potentially creditable hazardous waste pharmaceuticals are less stringent than the standards associated with the non-creditable hazardous waste pharmaceuticals. The main requirement includes utilizing and maintaining shipping papers to ensure confirmation of delivery to the reverse distributor. Shipments of hazardous waste pharmaceuticals to reverse distributors already must comply with U.S. Department of Transportation (DOT) requirements including documentation of shipments on a bill of lading (specifying the details of the shipment). There are no costs or benefits associated with this provision.
- 40 CFR 266.504 Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste: This provision describes the requirements for a facility that is a very small quantity generator for the total amount of hazardous waste generated at the site (both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste). Except for the required sewer provision in 40 CFR 266.505, a very small quantity generator has the option on whether to comply with subpart P or to continue to comply with the existing very small quantity generator requirements of 40 CFR 262.14. Based on Hazardous Waste Section knowledge and experience, it is anticipated that the very small quantity generator healthcare facilities will opt to comply with the existing generator requirements of 40 CFR 262.14 (and the required sewer prohibition). The development of the costs associated with the sewer prohibition (including the cost for very small quantity generators) is in Appendix D.

This provision also allows a very small quantity generator to send non-creditable hazardous waste pharmaceuticals off-site to another healthcare facility that is under the control of the same person that is managing non-creditable hazardous waste pharmaceuticals under subpart P. A provision (consolidation provision) already exists in the hazardous waste generator portion of the regulations (40 CFR 262) (adopted by reference at 15A NCA 13A .0107(a)) and allows hazardous waste from a very small quantity generator to be sent to a large quantity generator under the control of the same person. This provision in the hazardous waste generator section of the rules provides the same allowances as the one in subpart P. There are no costs or benefits associated with this provision.

- 40 CFR 266.505 Prohibition of sewerage hazardous waste pharmaceuticals: This provision prohibits the discharge of hazardous waste pharmaceuticals to the sewer system that passes through to a publicly-owned treatment works. Healthcare facilities (including very small

quantity generators) and reverse distributors are subject to this prohibition. The development of the costs associated with the sewer prohibition are in Appendix D.

- 40 CFR 266.506 Conditional exemption for hazardous waste pharmaceuticals that are also controlled substances and household hazardous waste pharmaceuticals collected in a take-back event or program: This provision provides an exemption for five pharmaceuticals (chloral/chloral hydrate, fentanyl sublingual spray, phenobarbital, testosterone gels/solutions, valium injectable/gel) that are classified as both RCRA hazardous waste pharmaceuticals and DEA regulated controlled substances. When these five pharmaceuticals are managed under the conditions of the exemption (specific DEA regulatory requirements for management and disposal), they are exempt from RCRA hazardous waste requirements. The development of the associated costs and benefits for this provision are in Appendix C and D.
- 40 CFR 266.507 Residues of hazardous waste pharmaceuticals in empty containers: This provision provides standards for determining whether specific containers/delivery devices which held hazardous waste pharmaceuticals are considered empty after the pharmaceutical has been dispensed. The provision applies to stock, dispensing, and unit dose containers; syringes; and intravenous (IV) bags. When the described standards are met, any residue remaining in the container/delivery device does not have to comply with RCRA hazardous waste requirements.

Currently, any container that held a P-listed hazardous waste (e.g. warfarin) must either be managed as a P-listed hazardous waste because of the residue remaining in the container or the container must be triple rinsed with the rinseate managed as a P-listed hazardous waste. Additionally, the residue remaining in the container (if it is not triple rinsed) counts towards the hazardous waste generator category for the facility. This provision (40 CFR 266.507) will allow the container to be considered empty once the pharmaceutical is dispensed. The container would not need to be managed as a P-listed hazardous waste or triple rinsed. This provision allows the facility no longer track the amount of P-listed residue that remains in the containers that once held a P-listed hazardous waste pharmaceutical. See *Summary of Unmonetized Benefits, Residues of Hazardous Waste Pharmaceuticals in Empty Containers* on page 33 for more information.

- 40 CFR 266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor: This provision provides requirements for shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor including (but not limited to): packaging and marking/labeling the containers and placarding of the vehicle by specific DOT requirements and manifesting the hazardous waste to a permitted or interim status hazardous waste treatment, storage, and disposal facility.

Currently, hazardous waste pharmaceuticals must meet the same DOT requirements and similar manifesting requirements when shipped from a healthcare facility or reverse distributor. The new provision allows the manifest to be marked with the waste code

"PHARMS" instead of individual waste codes for the hazardous waste pharmaceuticals. However, the facility must include the waste codes on the waste profiles to the treatment, storage and disposal facilities and to comply with the land disposal restriction requirements of 40 CFR 268 (adopted by reference at 15A NCAC 13A .0112) for each shipment of hazardous waste to the treatment, storage, and disposal facility. Ultimately, there is no cost or benefit associated with this new provision.

- 40 CFR 266.509 Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor: This provision provides the shipping requirements for potentially creditable hazardous waste pharmaceuticals from a healthcare facility or from a reverse distributor to another reverse distributor including (but not limited to): meeting DOT shipping requirements for hazardous materials (if applicable) and receiving delivery confirmation when received by the reverse distributor.

Currently, creditable pharmaceuticals that are shipped from a healthcare facility or from one reverse distributor to another meet the same DOT shipping requirements and are shipped on a bill of lading which tracks the shipment and provides confirmation of delivery. There is no cost or benefit associated with this new provision.

- 40 CFR 266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at reverse distributors: This provision applies to reverse distributors managing both evaluated hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals. After potentially creditable hazardous waste pharmaceuticals arrive at a reverse distributor, they are evaluated by the reverse distributor to determine whether they are eligible for manufacturer credit, or whether they need to be transferred to another reverse distributor for additional verification of manufacturer credit. Hazardous waste pharmaceuticals that need to be transferred to another reverse distributor for additional verification of manufacturer credit will continue to be considered potentially creditable hazardous waste pharmaceuticals.

Under current requirements, expired, recalled, and otherwise unused pharmaceuticals sent to reverse distributors for manufacturer credit are not considered a solid waste under RCRA (and therefore do not need to comply with hazardous waste requirements until a waste determination is made). Even though the RCRA hazardous waste requirements do not currently apply to the pharmaceuticals received at the facility, the reverse distribution facilities in North Carolina operate as large quantity generators of hazardous waste due to the management of the hazardous waste pharmaceuticals after they are evaluated. The North Carolina reverse distributors will continue to operate as large quantity generators after this rule is effective.

The Management Standards for Hazardous Waste Pharmaceuticals Rule requires reverse distributors (regardless of their hazardous waste category) to comply with the applicable subpart P provisions. Most subpart P requirements a reverse distributor must meet (e.g. closure requirements, inspections, manifests, land disposal restrictions, exception reports, personnel training) are ones that the facility is already complying with due to operating as

a large quantity generator. For instance, a reverse distributor is required to notify as operating under subpart P. Since the reverse distributor is already a large quantity generator, the notification of operating under subpart P may occur the next time the biennial report is submitted. A few requirements under subpart P are not ones that a large quantity generator is required to meet (e.g. maintaining an inventory and preventing unauthorized entry). North Carolina reverse distributors have indicated that an inventory is done as a business practice to track creditable pharmaceuticals that are at the site and the security component is required through DEA regulation. There is no cost/benefit associated with this provision.

15A NCAC 13A .0111(h) (continued from page 14) will be created for the Appendices to 40 CFR Part 266 that are currently found at 15A NCAC 13A .0111(g). There is no cost/benefit associated with this amendment.

General Facts and Assumptions Made for Cost/Benefit Analysis

General Facts:

Referenced throughout this document is EPA's October 2018 "Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals"³ (which will be referred to as EPA's Regulatory Impact Analysis). When referenced within this document, the EPA's Regulatory Impact Analysis page number is footnoted.

Also referenced in this document is EPA's September 2016 "Regulatory Impact Analysis of the Potential Costs, Benefits, and Other Impacts of the Final Hazardous Waste Generator Improvements Rule"⁴ (which will be referred to by its entire name, so it is not confused with the above Regulatory Impact Analysis). When referenced within this document, the page number will also be footnoted.

General Assumptions Made for Hourly Wage Rate Estimates:

The hourly employee compensation costs presented in this analysis reflects hourly mean wages reported either by the United States Bureau of Labor Statistics for specific occupational groups or the North Carolina State Employee Salary database for specific positions. Each hourly mean wage is based on a full-time employee working 40 hours a week, multiplied by a loaded wage rate factor of 1.43⁵. This multiplier represents the sum of two cost factors: (1) a fringe benefits (e.g., insurance, disability income protection, retirement benefits, sick leave, vacation, etc.) rate and (2) an overhead rate of 1.336.

North Carolina inflation adjusted wage growth rates were calculated by the North Carolina Office of State Budget and Management using wage growth and inflation projections from IHS Markit's⁶ September 2019 regional projections. The inflation adjusted wage growth rates are used in the wage rate for the calculations of cost over time. When the hourly wage is used in the explanation of the cost/benefits in the Appendices of this document, the hourly wage has been adjusted to reflect the first year of the effective proposed rules (anticipated 2020) or to reflect the date that cost/benefit will be accrued. The Cost and Benefit Summaries also incorporate the inflation-adjusted wage growth over time. Additional information on the development of the wage rate estimates are in Appendix A and Appendix B.

³ EPA's Regulatory Impact Analysis can be found at this website link: <https://www.regulations.gov/document?D=EPA-HQ-RCRA-2007-0932-0412>

⁴ EPA's September 2016 "Regulatory Impact Analysis of the Potential Costs, Benefits, and Other Impacts of the Final Hazardous Waste Generator Improvements Rule" can be found at this website link: <https://www.regulations.gov/document?D=EPA-HQRCRA-2012-0121-0313>

⁵ This factor was obtained from EPA's October 2018 Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals, page 55.

⁶ IHS Connect, <https://connect.ihs.com/home>

Summary of Costs

The costs are summarized by provision and the associated costs to the facility type (private versus federal, state, and local government) over an 11-year period. The cost summaries for each provision are refined to show impacts between state government healthcare facilities and the Hazardous Waste Section. The provisions with associated costs summarized in this section are:

- Sewer Prohibition
- Additional Training
- Notifications
- Management/Disposal of Hazardous Waste Pharmaceuticals that are DEA Controlled Substances
- Additional Time on Inspections, Complaints, and Compliance Assistance
- Enforcements
- Education and Outreach
- Loss of Fees

Appendix I contains detailed summaries of costs and benefits broken down for each facility type (private sector and federal, state and local government) by rule amendment along with the net impact and net present value of the 11-year impact for each individual facility type.

Sewer Prohibition

The sewer prohibition was effective nationwide on August 21, 2019 and prohibits healthcare facilities from sewer disposal of hazardous waste pharmaceuticals (a practice that was allowed prior to the prohibition). Hazardous waste pharmaceuticals generated at healthcare facilities (including very small quantity generator facilities) must now be disposed of through incineration. The development of the costs associated with the sewer prohibition is in Appendix D. The summary of the costs associated with having to incinerate hazardous waste pharmaceuticals instead of sewer disposing them are in Table 5, below.

Table 5

Cost Summary for Sewer Prohibition											
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Private Sector	\$29,067	\$51,582	\$33,957	\$33,957	\$33,957	\$33,957	\$33,957	\$33,957	\$33,957	\$33,957	\$33,957
Federal Government	\$2,753	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554
State Government (Healthcare Facilities)	\$3,247	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730
State Government (Hazardous Waste Section)	N/A										
Local Government	\$3,702	\$5,289	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764

The prohibition affects all facility types except for state government – Hazardous Waste Section (since this agency neither meets the definition of a healthcare facility nor disposes of hazardous waste pharmaceuticals). The private sector has the highest impact from this provision due to

having the most healthcare facilities fall into this facility type – 97.4% of healthcare facilities are private. Local government is the least affected by the sewer prohibition because local government facilities make up 0.5% of the healthcare facilities subject to this provision. Since the sewer prohibition was effective in August 2019, the cost was prorated for only 5 months in 2019. The costs associated with no longer being able to sewer dispose hazardous waste pharmaceuticals will recur annually. EPA's Regulatory Impact Analysis⁷ estimated the cost of sewer disposal to be \$1.06 per ton while incineration is \$2.26 per pound. The difference in cost for management is the reason this provision creates such a large cost impact.

Additional Training

Healthcare facilities that are large and small quantity generators will require some additional training because of the new requirements imposed by the Management Standards for Hazardous Waste Pharmaceuticals Rule. Healthcare facilities and reverse distributors already currently have specified regular training requirements (both awareness training for healthcare practitioners and specific training for personnel who handle hazardous waste and respond to hazardous waste emergencies) so this cost (of additional training due to the new requirements) is a one-time cost. The development of the costs associated with additional training is in Appendix C. The summary of the costs associated with having additional one-time training are in Table 6, below.

Table 6

Cost Summary for Additional Training											
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Private Sector		\$206,235									
Federal Government		\$13,509									
State Government (Healthcare Facilities)		\$20,043									
State Government (Hazardous Waste Section)	\$5,265	\$4,600									
Local Government		\$9,801									

The private healthcare and reverse distributors have the highest cost because the private sector healthcare facilities/reverse distributors make up 97.4% of the total healthcare facilities/reverse distributors. The Hazardous Waste Section will incur two years of internal training costs to familiarize staff with the new requirements. The training material development cost is included as part of the 2019 costs but not as a cost in 2020 which reduces the training cost for the Hazardous Waste Section in 2020 compared to 2019.

Notifications

A healthcare facility/reverse distributor must notify the Hazardous Waste Section of operating under the Management Standards for Hazardous Waste Pharmaceuticals Rule. This is a one-time

⁷ EPA's Regulatory Impact Analysis, pages 61-62

notification. A large quantity generator may notify as part of the next biennial report. A small quantity generator must notify within 60 days of becoming subject to the Management Standards for Hazardous Waste Pharmaceuticals Rule. Because large quantity generators are currently required to submit a biennial report, there is no cost or benefit associated with the provision for a large quantity generator to notify. The EPA Regulatory Impact Analysis⁸ estimates that the small quantity generator would incur a one-time notification cost of \$41.10 per facility. The development of the costs associated with notification is in Appendix C. The summary of the costs associated with notification of operating under the new rule are in Table 7, below.

Table 7

Cost Summary for Notifications											
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Private Sector		\$4,768									
Federal Government		\$41									
State Government (Healthcare Facilities)		\$123									
State Government (Hazardous Waste Section)		\$1,538									
Local Government		\$123									

The private sector costs are the highest since the private sector contains the most small quantity generator healthcare facilities (101 out of the total 105 small quantity generator healthcare facilities) that must notify. Additionally, included in the cost to notify are 15 private sector and 3 local government large quantity generator healthcare facilities that are able to reduce their generator category to small quantity generator (see Appendix B for more information). The cost to the Hazardous Waste Section is from the time to process the notifications (see Appendices B and C for more information).

Management/Disposal of Hazardous Waste Pharmaceuticals that are DEA Controlled Substances

While the DEA exemption creates the most benefit impact over time (see the *Summary of Benefits, DEA Exemption* on page 28), there is a period of time (11 months) between the time the sewer prohibition was effective (August 2019) and when the DEA exemption is effective (July 2020) that healthcare facilities must manage the hazardous waste pharmaceuticals that are DEA controlled substances through incineration and meet RCRA hazardous waste requirements. During these 11 months, there are costs associated with the management and disposal of the hazardous waste pharmaceuticals that are also DEA controlled substances. The development of the costs associated with the management/disposal of hazardous waste pharmaceuticals that are DEA controlled substances is in Appendix C. The summary of the costs associated with notification of operating under the new rule are in Table 8, on page 24.

⁸ EPA Regulatory Impact Analysis, page 57

Table 8

Cost Summary for Management/Disposal of Hazardous Waste Pharmaceuticals that are DEA Controlled Substances											
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Private Sector	\$28,980	\$34,500									
Federal Government	\$3,864	\$4,600									
State Government (Healthcare Facilities)	\$3,864	\$4,600									
State Government (Hazardous Waste Section)	N/A										
Local Government	\$5,796	\$6,900									

The private sector incurs the most cost since the private healthcare facilities make up 97.4% of the total healthcare facilities. The Hazardous Waste Section is not affected by this provision since the agency does not manage any DEA controlled substances. The costs occur only in 2019 and 2020 until the DEA exemption is effective. The costs are prorated since they are only incurred for 5 months in 2019 and 6 months in 2020.

Additional Time on Inspections, Complaints, and Compliance Assistance

The time spent on complaints, inspections, and compliance assistance will increase for a short period of time due to the new requirements imposed by the Management Standards for Hazardous Waste Pharmaceutical Rule. Even with the training and outreach, it will take Hazardous Waste Section staff and hazardous waste generators a while to become familiar and comfortable with the new requirements which will increase the time to complete complaint investigations, inspections and Compliance Assistance Visits as well as any subsequent reports or resulting Notices of Violations. The development of these costs are in Appendix E. The summary of the costs associated with this rule amendment are in Table 9, below.

Table 9

Cost Summary for Additional Time on Inspections, Complaints, and Compliance Assistance											
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Private Sector		\$4,635	\$4,738	\$4,841							
Federal Government		N/A									
State Government (Healthcare Facilities)		\$45	\$46	\$47							
State Government (Hazardous Waste Section)		\$3,940	\$3,940	\$4,039							
Local Government		N/A									

Only private sector and state government (both healthcare and the Hazardous Waste Section) will incur a cost. The private sector healthcare/reverse distributors have the highest cost because the private sector healthcare facilities make up 97.4% of the total facilities affected by this rule. The healthcare facilities/reverse distributors costs include the extra time spent with the Hazardous Waste Section Inspector during the Compliance Assistance Visit, complaint investigation, or inspection and any response to subsequent Notices of Violation resulting from the complaint/inspection. The Hazardous Waste Section will also incur the cost of the additional time spent on complaints and inspections and any follow-up reports or Notices of Violation as well as time spent on Compliance Assistance Visits. The costs will be an annual cost for the first three years the rule is effective. The cost increases over time due to the inflation adjusted wage rate of personnel.

Enforcement

Even with the training and outreach, there will be an increase in enforcements due to the new requirements imposed by the Management Standards for Hazardous Waste Pharmaceuticals Rule. The development of the costs for this rule amendment are in Appendix F. The summary of the costs associated with this rule amendment are in Table 10, below.

Table 10

Cost Summary for Enforcement											
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Private Sector					\$34,627						
Federal Government		N/A									
State Government (Healthcare Facilities)		N/A									
State Government (Hazardous Waste Section)					\$6,090						
Local Government		N/A									

This rule amendment will affect the private sector healthcare facility/reverse distributors and the Hazardous Waste Section. Since private sector healthcare facility/reverse distributors make up 97.4% of the total healthcare facilities/reverse distributors, it is assumed that this facility type will incur these costs (see Appendix F for more information on the assumptions made). The private healthcare facility/reverse distributor will incur the cost of the time spent responding to the enforcement action as well as the penalty assessed. The Hazardous Waste Section will incur the cost of the time spent on the additional enforcements. The costs will be an annual costs that is assumed to occur within the first five years the rule is effective (for purposes of this document the enforcement will occur in 2023). If the enforcement occurred in a different year, the cost may increase over time due to the inflation adjusted wage rate of personnel (or decrease if the enforcement occurs prior to 2023).

Education and Outreach

In an effort to help healthcare facilities/reverse distributors comply with the new requirements, the Hazardous Waste Section will provide additional training and outreach to the regulated community. The development of the costs for this rule amendment are in Appendix G. The summary of the costs associated with this rule amendment are in Table 11, below.

Table 11

Cost Summary for Education and Outreach											
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Private Sector		N/A									
Federal Government		N/A									
State Government (Healthcare Facilities)		N/A									
State Government (Hazardous Waste Section)		\$5,280	\$2,400	\$2,460	\$2,520	\$2,520					
Local Government		N/A									

The Hazardous Waste Section will incur a one-time cost for 2020 for the additional time spent on developing guidance information and training. Costs for presentations (60 hours per year) will recur annually thereafter for four more years. The cost for the development of guidance information is included in 2020 but not included in subsequent years – explaining the reduction in cost between 2020 and 2021. The change in the cost over period of 2021 through 2024 is due to the inflation adjusted wage rate of personnel.

Loss of Fees

Eighteen healthcare facilities (15 private and 3 local government) will be able to downgrade their hazardous waste generator category upon the provisions of the Management Standards for Hazardous Waste Pharmaceuticals Rule being effective in North Carolina. The 18 healthcare facilities will operate as a small quantity generator which has an annual fee of \$175 instead of a large quantity generator with an annual fee of \$1,400. The development of the costs associated with the reduction in fees are in Appendix B. The summary of the costs associated with this rule amendment are in Table 12, on page 27.

Table 12

Cost Summary for Loss of Fees											
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Private Sector		N/A									
Federal Government		N/A									
State Government (Healthcare Facilities)		N/A									
State Government (Hazardous Waste Section)		\$22,050	\$22,050	\$22,050	\$22,050	\$22,050	\$22,050	\$22,050	\$22,050	\$22,050	\$22,050
Local Government		N/A									

The private sector and local government healthcare facilities that will change their generator category will receive a benefit from not having to pay the large quantity generator fee (see the *Summary of Monetized Benefits, Reduction in Fees*, page 30). The Hazardous Waste Section will incur a cost annually due to the loss of the fees from the 18 facilities that are able to downgrade their hazardous waste generator category to small quantity generator.

Summary of Monetized Benefits

The benefits are summarized by provision and the associated benefits to the facility type (private versus federal, state, and local government) over an 11-year period. The benefits summaries for each provision are refined to show impacts between state government hazardous waste generators and the Hazardous Waste Section. The provisions with associated benefits summarized in this section are:

- Labeling
- DEA Exemption
- Not Being a Large Quantity Generator
- Reduction in Fees
- Enforcement

Appendix I contains detailed summaries of costs and benefits broken down for each facility type (private sector and federal, state and local government) by provision along with the net impact and net present value of the 11-year impact for each individual facility type.

Labeling

The container labeling requirements under the Management Standards for Hazardous Waste Pharmaceuticals are reduced compared to the current requirements. The development of the benefits associated with the reduced container labeling requirements is in Appendix B. The summary of the benefits associated with this rule amendment are in Table 13, on page 28.

Table 13

Benefit Summary for Labeling											
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Private Sector		\$502	\$1,026	\$1,049	\$1,072	\$1,095	\$1,122	\$1,148	\$1,174	\$1,200	\$1,227
Federal Government		\$14	\$28	\$29	\$29	\$30	\$31	\$32	\$32	\$33	\$34
State Government (Healthcare Facilities)		\$22	\$45	\$46	\$47	\$47	\$48	\$49	\$49	\$50	\$51
State Government (Hazardous Waste Section)		N/A									
Local Government		\$13	\$26	\$27	\$27	\$27	\$28	\$28	\$29	\$29	\$29

All facility types (private and federal, state, and local government) will receive an annual benefit from the reduced container labeling requirements beginning when the rule amendments are effective. The benefit is proportional to the number of facilities in each facility type. Private sector healthcare facilities will have the largest benefits since private sector healthcare facilities make up 97.4% of the total healthcare facilities. The benefit is prorated (for 6 months) for the first year the amendments are effective since the anticipated effective date is July 1, 2020. Federal and local government receive the lowest benefit due to the number of facilities (3 each) that are subject to this provision. The benefit increases over time due to the wage growth rate of personnel (see Appendix B, Table 22 for more information).

DEA Exemption

The Management Standards for Hazardous Waste Pharmaceuticals Rule provides a conditional exemption for hazardous waste pharmaceuticals that are also DEA controlled substances. When these hazardous waste/DEA pharmaceuticals are managed under the conditions of the exemption (specific DEA regulatory requirements for management and disposal), they are exempt from RCRA hazardous waste requirements. This exemption is not effective until authorized states adopt the provision (anticipated July 1, 2020).

Prior to the sewer prohibition effective date (August 21, 2019), hazardous waste pharmaceuticals that are also DEA controlled substances that were not fully dispensed to patients were sewerer for disposal (meeting both RCRA and DEA disposal requirements). Now that the RCRA sewer prohibition is effective, this waste stream is no longer allowed to be sewerer. Until the DEA exemption is effective, this waste stream is subject to full hazardous waste regulation and DEA requirements. The costs associated with the management of this waste stream are accounted for in the *Costs Summary, Management/Disposal of Hazardous Waste Pharmaceuticals that are DEA Controlled Substances* on page 23. Once the exemption is effective, the healthcare facilities (as long as they comply with DEA requirements) will no longer be required to comply with the RCRA hazardous waste requirements for this waste stream resulting in an annual benefit. The development of the benefits associated with the DEA exemption are in Appendix C. The summary of the benefits associated with this rule amendment are in Table 14, on page 29.

Table 14

Benefit Summary for DEA Exemption											
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Private Sector		\$34,500	\$69,000	\$69,000	\$69,000	\$69,000	\$69,000	\$69,000	\$69,000	\$69,000	\$69,000
Federal Government		\$4,600	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200
State Government (Healthcare Facilities)		\$4,600	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200
State Government (Hazardous Waste Section)		N/A									
Local Government		\$6,900	\$13,800	\$13,800	\$13,800	\$13,800	\$13,800	\$13,800	\$13,800	\$13,800	\$13,800

Since the disposal costs for hazardous waste pharmaceuticals that are also DEA controlled substances is so expensive, once the exemption from having to comply with the dual (RCRA and DEA) disposal is effective, all facility types will receive a benefit. Private healthcare facilities receive the largest benefit due to having the most healthcare facilities (97.4% of the healthcare facilities are in the private sector). The benefit for the first year the exemption is effective is prorated (for 6 months) since the anticipated effective date of the exemption is July 2020.

Not Being a Large Quantity Generator

Eighteen healthcare facilities (15 private and 3 local government) will be able to downgrade their hazardous waste generator category upon the provisions of the Management Standards for Hazardous Waste Pharmaceuticals Rule being effective in North Carolina. The development of the benefits associated with the reduction in generator category (from large quantity to small quantity) are in Appendix B. The summary of the benefits associated with this rule amendment are in Table 15, below.

Table 15

Benefit Summary for Not Being a Large Quantity Generator											
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Private Sector		\$51,139	\$51,610	\$59,302	\$52,228	\$60,243	\$52,920	\$61,262	\$53,451	\$62,476	\$54,357
Federal Government		N/A									
State Government (Healthcare Facilities)		N/A									
State Government (Hazardous Waste Section)		N/A									
Local Government		\$10,177	\$10,268	\$11,807	\$10,393	\$11,969	\$10,516	\$12,143	\$10,635	\$12,372	\$10,826

The private sector and local government healthcare facilities that will change their generator category will receive a benefit from not having to comply with the large quantity generator

requirements of maintaining a contingency plan, annual training with documented training records, or completing a biennial report. The benefits increase over time due to the wage growth rate of personnel (see Appendix B, Table 22 and 23). The private sector hazardous waste generators receive the most benefit since 15 private healthcare facilities (versus 3 from local government) are able to reduce their hazardous waste generator category.

Reduction in Fees

Also associated with not being a large quantity generator is not having to pay an annual large quantity generator fee (\$1,400). Eighteen facilities (15 private and 3 local government) will be able to downgrade their hazardous waste generator category upon the provisions of the Management Standards for Hazardous Waste Pharmaceuticals Rule being effective in North Carolina. The eighteen facilities will operate as a small quantity generator which has an annual fee of \$175. The benefits will occur annually. The development of the benefits associated with the reduction in fees are in Appendix B. The summary of the benefits associated with this rule amendment are in Table 16, below. The summary of the costs associated with this rule amendment are in *Summary of Costs, Loss of Fees* on page 26.

Table 16

Benefit Summary for Reduction In Fees											
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Private Sector		\$18,375	\$18,375	\$18,375	\$18,375	\$18,375	\$18,375	\$18,375	\$18,375	\$18,375	\$18,375
Federal Government		N/A									
State Government (Healthcare Facilities)		N/A									
State Government (Hazardous Waste Section)		N/A									
Local Government		\$3,675	\$3,675	\$3,675	\$3,675	\$3,675	\$3,675	\$3,675	\$3,675	\$3,675	\$3,675

The private sector healthcare facilities receive the most benefit from the reduction in the annual fees since 15 private healthcare facilities (versus the 3 local government facilities) are able to reduce their hazardous waste generator category.

Enforcement – Penalty Payments

Even with the training and outreach, there will be an enforcement (compliance order with penalty) issued due to the new requirements imposed by the Management Standards for Hazardous Waste Pharmaceuticals Rule. When a healthcare facility/reverse distributor is issued an enforcement with penalties, the county school system where that facility is located receives the compliance order penalty payment. The development of the benefits for this rule amendment are in Appendix F. The summary of the costs associated with this rule amendment are in *Summary of Costs, Enforcement*, on page 25. The summary of the benefits associated with this rule amendment are in Table 17, below.

Table 17

Benefit Summary for Enforcement (Penalties Received by Local School System)											
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Private Sector		N/A									
Federal Government		N/A									
State Government (Healthcare Facilities)		N/A									
State Government (Hazardous Waste Section)		N/A									
Local Government					\$34,147						

The result of the rule amendment will affect the local government and specifically the county school system since they will receive the penalty payments from the enforcement action. The benefits will be annual costs for one year and will likely occur within the first five years the rule is effective. For purposes of this document, the enforcement will occur in 2023.

Summary of Unmonetized Benefits

Protection of Human Health and the Environment

Based on the Hazardous Waste Section knowledge and experience, the sewer prohibition will protect human health and the environment by reducing the amount of hazardous waste pharmaceuticals that enter the publicly owned wastewater treatment system and subsequently the surface water. An estimated 32 tons of hazardous waste pharmaceuticals a year will be kept from entering waterways in North Carolina on an annual basis by prohibiting all facilities subject to the rule from sewerage them.

EPA's Regulatory Impact Analysis⁹ states the sewer prohibition has a positive environmental impact, but that it is non-monetized (unquantifiable) benefits: "... there are negative externalities which affect the environment that are associated with the sewerage of hazardous waste pharmaceuticals. A negative environmental externality occurs when one party's actions impose uncompensated costs in the form of negative environmental effects on another party. When hazardous waste pharmaceuticals are sewerage rather than managed at a permitted hazardous waste disposal facility, they are frequently released by wastewater treatment plants into U.S. surface waters, exposing human populations and ecosystems to harmful contaminants. The rule will address these negative externalities by prohibiting the sewerage of hazardous waste pharmaceuticals and internalizing the costs of their safe disposal."

EPA's Regulatory Impact Analysis¹⁰ continues "Sewerage is one of the most harmful disposal methods due to the concentration of active pharmaceutical ingredients (APIs) in surface waters, as well as the increased potential for dissolution in water and absorption by humans and other

⁹ EPA's Regulatory Impact Analysis, Page 2-3

¹⁰ EPA's Regulatory Impact Analysis, Page 91

organisms. Additionally, while APIs enter U.S. surface waters through many pathways (including human excretion and excretions from concentrated animal feeding operations [CAFOs], among others) and the contribution of sewerage compared to these other sources is uncertain, sewerage of hazardous waste pharmaceuticals at healthcare facilities represents a direct conduit of APIs to surface water and is a readily avoidable contamination pathway.

A reduction in sewerage may benefit aquatic organisms by reducing their exposure to potentially harmful APIs and, by extension, reducing the incidence of any adverse effects associated with exposure to these compounds. With respect to human populations, although the few studies examining the human health risks of pharmaceuticals in the environment suggest that such risks are limited, it is uncertain whether the findings in these studies, which focus on pharmaceuticals that are not considered hazardous when disposed, apply to hazardous waste pharmaceuticals as well. Thus, to the extent that hazardous waste pharmaceuticals in the environment pose risks to human health, the rule may result in health improvements for human populations. While it is not possible to quantify the changes in ecological and human health risk associated with changes in the management of hazardous waste pharmaceuticals resulting from the rule, the estimated reduction in sewerage resulting from the rule may shed light on the potential magnitude of these risk impacts."

The enforcement and compliance of the sewer prohibition will determine the ultimate effectiveness of this provision and the associated benefits. The Hazardous Waste Section will review documentation and records for the healthcare facility and reverse distributor to ensure that the facility has training and procedures in place to no longer sewer dispose the hazardous waste pharmaceuticals and disposal records indicating that hazardous waste pharmaceuticals are incinerated. Healthcare facilities and reverse distributors that operate as a small or large quantity generator of hazardous waste are required to maintain hazardous waste manifests for three years. Hazardous waste manifests from years prior to the effective date of the sewer prohibition will be reviewed and compared to the manifests after the effective date of the sewer prohibition to evaluate compliance. Compliance with the sewer prohibition may be difficult to enforce since the amounts of hazardous waste pharmaceuticals that are sewered prior to the sewer prohibition were often unknown quantities and any available amounts were typically estimates. Very small quantity generator healthcare facilities are not required to maintain documentation indicating proper disposal of hazardous waste pharmaceuticals in lieu of sewer disposal making it difficult to determine compliance with the provision. Additionally, hazardous waste pharmaceuticals are generated in small amounts in lots of different places in a healthcare facility that also offer many sewerage options (e.g. toilets and/or sinks in most rooms throughout the facility). This increases the possible mismanagement of hazardous waste pharmaceuticals through easy access to sewer disposal. Ultimately, the on-site training of facility personnel will be key in achieving compliance with the sewer prohibition.

Maintaining State Authorization

A benefit of adopting the required provisions of the Management Standards of Hazardous Waste Pharmaceutical Rule is that the State Authorization will be maintained, and North Carolina will continue to operate the Hazardous Waste Management Program in lieu of EPA.

If the provisions of the federal Management Standards of Hazardous Waste Pharmaceutical Rule, are not adopted, the North Carolina Hazardous Waste Program would be put in jeopardy and in effect, this would create economic impact to private entities and federal, state, and local government. By not adopting the provisions of the Management Standards of Hazardous Waste Pharmaceutical Rule, grant funding received from EPA to implement the Authorized State Program could be reduced until the state meets the authorization requirements or EPA could revoke the North Carolina Hazardous Waste Management Program State Authorization and implement the program on the federal level from EPA, Region 4 in Atlanta, Georgia. If EPA revoked the State Authorization in North Carolina, the requirements of this subject federal regulation are already in effect on the federal level and EPA would continue to have oversight (which does not impact the regulated community), however, there would be many other negative impacts to the North Carolina regulated entities, the regulators, and the general public.

Established relationships, rapport and lines of communication between the regulated entities and regulators as well as other local regulatory agencies would be lost. Also, lost would be the ability and opportunities to engage with stakeholders and work through issues on a local level. Local issues are often interpreted differently or have less priority once they are removed from the local level. The Hazardous Waste Section currently has the ability to directly address local issues and make fast and informed decisions that are not "boiler plate" for the often, unique problems, that arise. The Hazardous Waste Section has knowledge of historical issues and the issues important to citizens and stakeholder groups. Currently, the Hazardous Waste Section has the opportunity to provide compliance assistance quickly and because of the Section's historical and regional knowledge of the site or information specific to the local area (e.g. county or city stormwater, wastewater or other state agencies) the relationship between the regulator and the regulated entities is often beneficial. Having the regulators located close to the regulated community reduces response time in an emergency or time critical situation like a complaint investigation. Having a physical presence improves the level of compliance.

Residues of Hazardous Waste Pharmaceuticals in Empty Containers

EPA's Regulatory Impact Analysis¹¹ states: "...healthcare facilities will now be able to consider containers that once held acute hazardous waste pharmaceuticals empty under RCRA regulations by removing the acute hazardous waste pharmaceutical. Previously, facilities generally had to triple rinse containers that once held acute hazardous waste or manage the residues in the containers as hazardous waste. EPA expects that this change will allow some healthcare facilities to generate and manage less waste that is considered hazardous waste and thus will experience a change in their generator category. However, there is inherent uncertainty surrounding the volume of acute hazardous waste generated by healthcare facilities that can be attributed to containers, and thus EPA was unable to quantify these potential cost savings."

The new provision for residues of hazardous waste pharmaceuticals in empty container addresses stakeholder concerns about the difficulty in determining the amount of residue in containers that once held an acute hazardous waste and overregulation caused by having to manage this residue as an acute hazardous waste. Triple rinsing can be impractical with certain medical devices, such as syringes and paper cups, so healthcare facilities often end up managing these containers as

¹¹ EPA's Regulatory Impact Analysis, page 70

hazardous waste, which can result in the facilities being subject to the most stringently regulated generator category as a large quantity generator of hazardous waste.

This provision supports the elimination of sewerage of pharmaceuticals. EPA's 2015 proposed Management Standards for Hazardous Waste Pharmaceuticals¹² indicated that "in a healthcare setting, when containers are triple rinsed, the rinseate will be poured down the drain which is not a good environmental practice. We think it is important that the residues be managed in a more controlled manner—such as municipal solid waste management—rather than poured down the drain."

Existing hazardous waste regulations for residues of hazardous waste in empty containers (40 CFR 261.7 adopted by reference at 15A NCAC 13A .0106(a)) apply to all sizes of containers, but these rules were developed with larger, industrial-sized containers in mind. EPA's 2015 proposed Management Standards for Hazardous Waste Pharmaceuticals Rule¹³ states "For the most part, the containers that hold pharmaceuticals range in size from a few milliliters (e.g., packaging for nicotine gum, paper cups used to dispense pharmaceuticals to in-patients) to a liter (e.g., bottles that hold bulk quantities of pills). In rare circumstances, containers with pharmaceuticals are as large as two or three liters (e.g., powders that are reconstituted with water). This differs significantly from the 55-gallon drums that are typically used in other sectors that generate hazardous waste. Consequently, the amount of residues in the containers was anticipated to be much more substantial than is the case for containers typically used for pharmaceuticals."

Also included in the 2015 proposed Management Standards for Hazardous Waste Pharmaceuticals Rule¹⁴, EPA received and evaluated data from three stakeholders demonstrating that there is very little residue remaining in fully dispensed containers of pharmaceuticals. Evaluation by stakeholders of residue left in warfarin (an acute hazardous waste) pill bottles indicated that the total weight of residues remaining in the containers after they were emptied of the warfarin pills is negligible.

With the amount of residue that remains in the empty pharmaceutical containers being negligible the risk (and associated costs) are minimal even when residue in the empty container is managed as a solid waste versus as a hazardous waste. This provision offers unquantifiable benefits of improved compliance rate with the sewer prohibition while reducing the burden on the healthcare facility from complicated calculations involving residue in containers and possible overregulation as a large quantity generator of hazardous waste.

¹² Proposed Management Standards for Hazardous Waste Pharmaceuticals (80 FR 58014; September 25, 2015), page 58052 found at this link: <https://www.govinfo.gov/content/pkg/FR-2015-09-25/pdf/2015-23167.pdf>

¹³ Proposed Management Standards for Hazardous Waste Pharmaceuticals (80 FR 58014 ; September 25, 2015), page 28052

¹⁴ Proposed Management Standards for Hazardous Waste Pharmaceuticals (80 FR 58014 ; September 25, 2015), page 28052-58054

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Appendix A

Development of Inflation Adjusted Wage Rate Estimates

The United States Department of Labor, Bureau of Labor Statistics (BLS), website was reviewed to determine the Standard Occupational Classification¹⁵ (SOC) codes for the specific positions (occupational groups) described in this analysis. The occupational groups and SOC codes relevant to this analysis are in Table 18, below.

Table 18

Occupational Group	Standard Occupational Classification (SOC) Code	Title of Position Used in this Document for Cost/Benefit Analysis
Environmental Scientists and Specialists, Including Health ¹⁶	192041	Environmental Specialist
Environmental Science and Protection Technicians, Including Health ¹⁷	194091	Environmental Technician

The most current (May 2018) BLS national¹⁸ and North Carolina¹⁹ Occupational Employment and Wage Estimates were both reviewed for the specific SOC codes noted above to determine the wage estimates for each occupational group.

The BLS national wage estimates are further divided into federal, state and local government categories (Occupational Employment Statistics (OES) designation), but only for some of the occupational groups. The Environmental Scientists and Specialists occupational group offer OES designation for federal, state and local government. The Environmental Science and Protection Technicians occupational group offers OES designation for state and local government. The state specific wage data does not offer further OES designation into federal, state or local government. Even though the state specific information does not offer data specific to federal, state and local government, because the national Occupational Employment and Wage Estimates are significantly higher than the North Carolina specific data, the state specific wage estimates are used in this analysis since they seem appropriately representative. Table 19, on page 34, provides the wage estimates for the occupational groups reviewed.

¹⁵ Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment Statistics, 2018 Standard Occupational Classification (SOC) code, November 28, 2017, <https://www.bls.gov/soc/2018/home.htm>

¹⁶ Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wages, May 2018, 19-2041 Environmental Scientists and Specialists, Including Health: <https://www.bls.gov/oes/current/oes192041.htm>

¹⁷ Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wages, May 2018, 19-4091 Environmental Science and Protection Technicians, Including Health, <https://www.bls.gov/oes/current/oes194091.htm>

¹⁸ Bureau of Labor Statistics, U.S. Department of Labor, May 2018 State National Occupational Employment and Wage Estimates https://www.bls.gov/oes/current/oes_nat.htm

¹⁹ Bureau of Labor Statistics, U.S. Department of Labor, May 2018 State Occupational Employment and Wage Estimates North Carolina: https://www.bls.gov/oes/current/oes_nc.htm

Table 19

National and North Carolina Specific Wage Estimates for Occupational Groups from Bureau of Labor Statistics May 2018						
Occupational Group & Standard Occupational Classification (SOC) Code	National Annual Mean Wage* (with OES Designation -if available)		National Hourly Mean Wage (with OES Designation -if available)		North Carolina Annual Mean Wage*	North Carolina Hourly Mean Wage
Environmental Scientists and Specialists, Including Health (192041)	General	\$75,580	General	\$37.30	\$64,850	\$31.18
	Federal	\$104,820	Federal	\$50.39		
	State	\$66,650	State	\$32.04		
	Local	\$71,770	Local	\$34.51		
Environmental Science and Protection Technicians, Including Health (194091)	General	\$50,350	General	\$24.21	\$42,810	\$20.58
	Federal	Not Available	Federal	Not Available		
	State	\$48,200	State	\$23.17		
	Local	\$54,570	Local	\$26.23		

*Annual wages have been calculated by multiplying the hourly mean wage by 2,080 hours.

Salaries for Hazardous Waste Section staff are determined using 2019 North Carolina state employee salary data²⁰. The Hazardous Waste Section estimated annual salaries for positions involved in this analysis are included in Table 20, below.

Table 20

Hazardous Waste Section Positions and Annual Salary Estimates for 2019	
Position	Annual Salary
Inspector	\$57,470
Processing Assistant	\$35,500
Hazardous Waste Section Average Salary	\$57,311

The hourly employee compensation costs presented in this analysis reflects hourly mean wages reported as described above -- either by the U.S. Bureau of Labor Statistics for each occupational group or the North Carolina State Employee Salary database. Each hourly mean wage is based on a full-time employee working 40 hours a week, multiplied by a loaded wage rate factor of 1.43²¹. This multiplier represents the sum of two cost factors: (1) a fringe benefits (e.g., insurance, disability income protection, retirement benefits, sick leave, vacation, etc.) rate and (2) an overhead rate of 1.336.

²⁰ 2019 North Carolina state employee salary data was obtained from the State Personnel Salary database at this website link: <https://www.newsobserver.com/news/databases/state-pay/article11865482.html>

²¹ This factor was obtained from EPA's October 2018 Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals, page 55 (<https://www.regulations.gov/document?D=EPA-HQ-RCRA-2007-0932-0412>)

North Carolina inflation adjusted wage growth rates were calculated by the North Carolina Office of State Budget and Management using wage growth and inflation projections from IHS Markit’s²² September 2019 regional projections. The inflation adjusted wage growth rates are used in the wage rate for the calculations of cost over time. When the hourly wage is used in the explanation of the cost/benefits in the Appendices of this document, the hourly wage has been adjusted to reflect the first year of the effective proposed rules (anticipated 2020) or to reflect the date that cost/benefit will be accrued. The Cost and Benefit Summaries also incorporate the inflation-adjusted wage growth over time. For this document, the following wage rate estimates will be used:

Environmental Specialist (Occupational Group – Environmental/Scientist, Including Health): The estimated private sector and federal, state and local government salary of an Environmental Specialist is estimated in 2018 at \$64,850 per year. This salary multiplied by the loaded wage rate factor of 1.43 provides the salary with benefits of: \$92,736 or \$45/hour. The 2020 loaded hourly rate for this position will be \$45/hour. Below is an example of the inflation adjusted wage rate over time for this position.

Inflation Adjusted Wage Rate Estimated Over Time for Environmental Specialist													
Year	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Hourly Wage	\$45	\$44	\$45	\$46	\$47	\$48	\$49	\$50	\$51	\$52	\$54	\$55	\$56

Environmental Technician (Occupational Group – Environmental Science and Protection Technicians, Including Health): The estimated private sector and federal, state and local government salary of an Environmental Technician is estimated in 2018 at \$42,810 per year. This salary multiplied by the loaded wage rate factor of 1.43 provides the salary with benefits of: \$61,218 or \$29/hour. The 2020 loaded hourly rate for this position will be \$30/hour. Below is an example of the inflation adjusted wage rate over time for this position.

Inflation Adjusted Wage Rate Estimated Over Time for Environmental Technician													
Year	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Hourly Wage	\$29	\$29	\$30	\$30	\$31	\$32	\$32	\$33	\$34	\$35	\$35	\$36	\$37

²² IHS Connect, <https://connect.ihs.com/home>

Hazardous Waste Section Employees

- **Hazardous Waste Section Inspector:** The average salary in 2019 is estimated at \$57,470 per year. This salary multiplied by the loaded wage rate factor of 1.43 provides the salary with benefits of: \$82,182 or \$40/hour. The 2020 loaded hourly rate for this position will be \$40/hour. Below is an example of the inflation adjusted wage rate over time for this position.

Inflation Adjusted Wage Rate Estimated Over Time for Hazardous Waste Section Inspector												
Year	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Hourly Wage	\$40	\$40	\$40	\$41	\$42	\$42	\$43	\$44	\$44	\$45	\$46	\$46

- **Hazardous Waste Section Processing Assistant:** The average salary in 2019 is estimated at \$35,500 per year. This salary multiplied by the loaded wage rate factor of 1.43 provides the salary with benefits of: \$50,765 or \$24/hour. The 2020 loaded hourly rate for this position will be \$25/hour. Below is an example of the inflation adjusted wage rate over time for this position.

Inflation Adjusted Wage Rate Estimated Over Time for Hazardous Waste Section Processing Assistant												
Year	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Hourly Wage	\$24	\$25	\$25	\$25	\$26	\$26	\$26	\$27	\$27	\$28	\$28	\$29

- The average salary in 2019 in the Hazardous Waste Section²³ is estimated at \$57,311 per year. This salary multiplied by the loaded wage rate factor of 1.43 provides the salary with benefits of \$81,955 or \$39/hour. The 2020 loaded hourly rate for this position will be \$40/hour. Below is an example of the inflation adjusted wage rate over time for this position.

Inflation Adjusted Wage Rate Estimated Over Time for Hazardous Waste Section Average Salary												
Year	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Hourly Wage	\$39	\$40	\$40	\$41	\$42	\$42	\$43	\$43	\$44	\$45	\$45	\$46

Additional estimated wage growth rates over time are in Appendix B as it pertains to training, biennial report preparation and labeling for Environmental Specialists.

²³ All 2019 Hazardous Waste Section staff salaries were averaged to obtain this number. 2019 North Carolina state employee salary data was obtained from the State Personnel Salary database at this website link: <http://www.newsobserver.com/news/databases/state-pay/>

Appendix B

Costs/Benefits Associated with Being Able to Reduce Generator Category

The Management Standards for Hazardous Waste Pharmaceuticals Rule applies to all healthcare facilities that generate, accumulate, or otherwise handle hazardous waste pharmaceuticals and are small quantity generators or large quantity generators when total volume of hazardous waste (both pharmaceutical and non-pharmaceutical hazardous waste) are calculated.

Once a healthcare facility determines whether the Management Standards for Hazardous Waste Pharmaceuticals Rule apply (by calculating the total volume of hazardous waste generated at the site [both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste]), this rule allows hazardous waste pharmaceuticals to not count towards the hazardous waste generator category. When a healthcare facility operates in compliance with subpart P, a second calculation is then done to determine the hazardous waste generator category based only on the amount of non-pharmaceutical hazardous waste generated at the facility.

After this rule is effective in North Carolina, it is anticipated that some of the healthcare facilities that are currently operating as large quantity generators of hazardous waste will be able to downgrade their hazardous waste generator category to small quantity generator. Based on Hazardous Waste Section knowledge of the healthcare facilities currently operating as a large quantity generator of hazardous waste, 15 private sector and 3 local government healthcare facilities will likely be able to renotify as a small quantity generator once the rule is effective in North Carolina. The healthcare facilities that will remain a large quantity generator (2 federal government and 2 state government facilities) will remain a large quantity generator due to the amount of non-pharmaceutical hazardous waste generated at the facility.

The 15 private sector and 3 local government health care facilities receive the benefit of being able to reduce their original hazardous waste category from large quantity generator to small quantity generator and not having to comply with the large quantity generator requirements of: maintaining a contingency plan, annual training with documented training records, completing a biennial report or paying large quantity generator annual fees. The benefits increase over time due to the inflation adjusted wage rate of personnel. The private sector hazardous waste generators receive the most benefit since 15 private healthcare facilities are able to reduce their hazardous waste generator category. It is assumed that these 18 facilities will downgrade their generator category as soon as the Management Standards for Hazardous Waste become effective.

The loaded hourly wages shown below and used in the cost and benefit summaries have been adjusted for inflation. Additional inflation adjusted hourly wage information can be found in Appendix A. Examples of how the costs and benefits were calculated for 2020 are described on page 41.

Table 21

Healthcare Facilities and Reverse Distributors in North Carolina by Hazardous Waste Generator Category Anticipated After Adoption of Rule (July 1, 2020)					
Category of Hazardous Waste Generator	Number of Healthcare Facility/Reverse Distributor Hazardous Waste Generators – Private Sector	Number of Healthcare Facility Hazardous Waste Generators – Federal Government	Number of Healthcare Facility Hazardous Waste Generators – State Government	Number of Healthcare Facility Hazardous Waste Generators – Local Government	Total Number of Healthcare Facility/Reverse Distributor Hazardous Waste Generators in North Carolina
Large Quantity Generator	5	2	2	0	9
Small Quantity Generator	116	1	3	3	123
Very Small Quantity Generator	432	2	2	0	436*
Total	553	5	7	3	568

Cost for Notification

The EPA Regulatory Impact Analysis²⁴ estimates that the small quantity generator would incur a one-time notification cost of \$41.10 per facility.

Private Healthcare Facilities:

- Large quantity generators able to renotify as small quantity generator (and of operating under subpart P): 15 facilities x \$41.10 = \$616.50
This is a one time cost that will occur in 2020.

State Government – Hazardous Waste Section

- 18 notifications will be processed x 0.5 hours = 9 hours x \$25/hour = \$225
This is a one time cost that will occur in 2020.

Local Government - Healthcare Facilities:

- Large quantity generators able to renotify as small quantity generator (and of operating under subpart P): 3 facilities x \$41.10 = \$123.30
This is a one time cost that will occur in 2020.

Training:

Currently, a large quantity generator must conduct and document annual hazardous waste training. A small quantity generator must conduct training (however it is less extensive than the large quantity generator training) and there is no requirement to document the training. EPA’s September 2016 Regulatory Impact Analysis of the Potential Costs, Benefits, and Other Impacts

²⁴ EPA Regulatory Impact Analysis, page 57

of the Final Hazardous Waste Generator Improvements Rule²⁵ estimated the benefit received by a small quantity generator when they were able to utilize the episodic generator provision and not have to comply with the training requirements for a large quantity generator. The estimated benefit was \$2,468 for small quantity generators that avoided becoming large quantity generators. This same benefit translates when a generator can downgrade their generator category from large quantity generator to small quantity generator. A small quantity generator that does not have to operate as a large quantity generator will receive this benefit annually. Table 22 provides the estimated wage growth rate over time²⁶ for training (also for biennial report and labeling) for an Environmental Specialist.

Table 22

Wage Growth Rate Estimated Over Time for Training, Biennial Report, and Labeling for Environmental Specialist												
Year	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
State & Local Government	1.41%	0.99%	1.40%	1.41%	1.47%	1.41%	1.52%	1.51%	1.50%	1.52%	1.64%	1.69%
Professional, Scientific, and Technical Services	-0.98%	1.67%	2.13%	2.18%	2.18%	2.21%	2.43%	2.34%	2.24%	2.21%	2.26%	2.19%

Contingency Plan:

Currently, a large quantity generator must have a contingency plan. A small quantity generator does not have a requirement to have or maintain a contingency plan. Instead a small quantity generator must post specific emergency information by a phone at the facility or in areas where hazardous waste is generated and accumulated. In the 2017 NCDEQ Fiscal Impact Analysis for the Hazardous Waste Generator Improvements Rule²⁷, the estimated cost of a contingency plan by type of facility is based on the estimates made in Appendix C of the 2017 Fiscal Impact Analysis. It is assumed that this generator would have a contingency plan that falls in the regular (not extensive) category (= 20 hours x salary of Environmental Specialist). The generator that can downgrade their generator category from a large to a small quantity generator receives an annual benefit of not having to have and maintain a contingency plan.

Biennial Report:

Currently, a large quantity generator must submit a biennial report on every even numbered year. A small quantity generator does not have a requirement to submit a biennial report. EPA’s September 2016 Regulatory Impact Analysis of the Potential Costs, Benefits, and Other Impacts of the Final Hazardous Waste Generator Improvements Rule²⁸ estimates that the biennial report costs from \$412 to \$559 per large quantity generator who is required to submit. For this document, an average (\$486) of the EPA’s September 2016 Regulatory Impact Analysis of the Potential

²⁵ EPA’s September 2016 Regulatory Impact Analysis of the Potential Costs, Benefits, and Other Impacts of the Final Hazardous Waste Generator Improvements Rule; page 4-13

²⁶ IHS Connect, <https://connect.ihs.com/home>

²⁷ The 2017 NCDEQ Fiscal Impact Analysis for the Hazardous Waste Generator Improvements Rule can be found at this link: https://files.nc.gov/ncosbm/documents/files/DEQ_2017-09-07.2.pdf

²⁸ EPA’s September 2016 Regulatory Impact Analysis of the Potential Costs, Benefits, and Other Impacts of the Final Hazardous Waste Generator Improvements Rule; page 4-15

Costs, Benefits, and Other Impacts of the Final Hazardous Waste Generator Improvements Rule range (\$412 to \$559) will be used. Based on Hazardous Waste Section knowledge and experience, it is assumed that the Environmental Specialist would be completing the biennial report. This is a one-time cost savings per biennial report cycle (every other year on even numbered years). Table 22, on page 42 provides the estimated wage growth rate over time for biennial report preparation for an Environmental Specialist. Table 23 estimates the biennial report costs over time factoring in the estimated wage growth.

Table 23

Biennial Report Costs with Wage Growth Rate Estimated Over Time for Environmental Specialist												
Year	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
State & Local Government	\$474.58	\$479.29	\$485.99	\$492.84	\$500.10	\$507.13	\$514.82	\$522.58	\$530.43	\$538.52	\$547.36	\$556.60
Professional, Scientific, and Technical Services	\$463.42	\$471.17	\$481.22	\$491.70	\$502.43	\$513.56	\$526.04	\$538.36	\$550.44	\$562.59	\$575.31	\$587.94

Benefit for Not Being a Large Quantity Generator

Private Healthcare Facilities:

- Training: (15 facilities x \$2,468) (1+ estimated wage growth for 2020 of 1.67%) = \$37,639
- Contingency Plan: 15 facilities x 20 hours x \$45/hour = \$13,500

These two benefits recur annually starting in 2020.

- Biennial Report: 15 facilities x \$491.70 = \$7,375.55

This benefit occurs every other year on even numbered years (starting in 2022).

Local Government Healthcare Facilities:

- Training: (3 facilities x \$2,468)(1+estimated wage growth for 2020 of .99%) = \$7,477
- Contingency Plan: 3 facilities x 20 hours x \$45/hour = \$2,700

These two benefits recur annually starting in 2020.

- Biennial Report: 3 facilities x \$492.84 = \$1,479

This benefit occurs every other year on even numbered years (starting in 2022).

Costs and Benefits for Facilities that are able to operate as a small quantity generator instead of a large quantity generator due to the Management Standards of Hazardous Waste Pharmaceuticals Rule also include a reduction in annual fees. The annual fee for a large quantity generator is \$1,400 and for a small quantity generator is \$175. Hazardous Waste Section annual fees are never prorated. The entire fee is applied even if a hazardous waste generator changes generator categories mid fee cycle.

Cost for Loss of Fees

State Government – Hazardous Waste Section loss of annual fees

- 18 facilities x (\$1,400 - \$175) = \$22,050

This is a recurring loss that happens annually starting in 2020.

Benefit for Reduction in Fees:

Private Healthcare Facilities:

- Large quantity generators able to renotify as small quantity generator will pay an annual fee of \$175 instead of \$1400: 15 facilities x (\$1,400- \$175) = \$18,375
This is an annual recurring benefit starting in 2020.

Local Government - Healthcare Facilities:

- Large quantity generators able to renotify as small quantity generator will pay an annual fee of \$175 instead of \$1400: 3 facilities x (\$1,400- \$175) = \$3,675
This is an annual recurring benefit starting in 2020.

Appendix C

Development of Costs/Benefits for Healthcare Facilities and Reverse Distributors

The Management Standards for Hazardous Waste Pharmaceuticals Rule requires healthcare facilities that operate as a large quantity or small quantity hazardous waste generator to meet specific requirements associated with the management of non-creditable and potentially creditable hazardous waste pharmaceuticals.

Non-creditable hazardous waste pharmaceuticals are used, partially used, or expired (beyond one year) prescription hazardous waste pharmaceuticals used in patient care and discarded by healthcare facilities. This type of hazardous waste pharmaceutical has no reasonable expectation to receive a manufacturer credit and must be sent to a permitted or interim status hazardous waste treatment, storage and disposal facility. A potentially creditable hazardous waste pharmaceutical are expired (for less than one year), recalled, and otherwise unused pharmaceuticals that have a reasonable potential to receive manufacturer credit. Potentially creditable hazardous waste pharmaceuticals may be sent to reverse distributors for evaluation for manufacturer credit.

There are some large quantity generator healthcare facilities that will be able to downgrade their hazardous waste generator category due to the new provisions. The facilities that change their generator category from large quantity to small quantity generator when the Management Standards for Hazardous Waste Pharmaceuticals Rule is effective in North Carolina will submit a notification to change their generator category and at this time will also notify as operating under subpart P. The costs and benefits associated with downgrading the generator category (including notification) are discussed in Appendix B.

Healthcare facilities that are very small quantity generators (based on the total amount of hazardous waste generated at the facility) have an option on complying with subpart P (except for the sewer prohibition) or continue to comply with the existing very small quantity generator requirements. Based on Hazardous Waste Section knowledge of the healthcare facilities that are currently operating as very small quantity generators, it is assumed that they will continue to operate under the existing very small quantity requirements described at 40 CFR 262.14, adopted by reference at 15A NCAC 13A .0106(a). There will be no cost or benefit associated with the very small quantity generators except for the cost of complying with the required sewer prohibition. The costs associated with the sewer prohibition are discussed in Appendix D.

Healthcare facilities that are small and large quantity generators of hazardous waste that will operate under subpart P have some requirements that will align with current hazardous waste generator requirements resulting in no cost or benefit to the healthcare facility or the Hazardous Waste Section. Requirements that are similar between subpart P (for healthcare facilities) and the current hazardous waste generator requirements include waste determinations; container management (closed, structurally sound, compatible with its contents and other wastes, and lacks evidence of leakage, spillage, or damage); land disposal restrictions; reporting and recordkeeping (manifests, exception reporting), and ability for a very small quantity generator to ship waste to a

facility under the same control. Since these new provisions align with current provisions, there is no cost or benefit associated with them.

Healthcare facilities operating under subpart P must provide training to personnel managing non-creditable pharmaceuticals that ensures that the personnel are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies. Overall, the new provision aligns with current training requirements for small quantity generators. Any healthcare facilities remaining a large quantity generator (due to the non-pharmaceutical hazardous waste) already has training requirements that meet and exceed the training requirement for non-creditable hazardous waste pharmaceuticals. There will only be a one time cost associated with the additional training requirements for the first year the provisions are effective since the training content will be changed (from managing hazardous waste pharmaceuticals under the hazardous waste generator requirements to subpart P requirements). Any facilities that are able to change their generator category will have the benefit of not having to meet large quantity generator requirements accounted for in Appendix B.

The following requirements of subpart P for healthcare facilities managing non-creditable hazardous waste pharmaceuticals will have costs/benefits associated with them. The loaded hourly wages shown below and used in the cost and benefit summaries have been adjusted for inflation. Additional inflation adjusted hourly wage information can be found in Appendix A. It is assumed the Hazardous Waste Section Processing Assistant will be processing the notifications.

Notification

A healthcare facility must notify the Hazardous Waste Section of operating under subpart P. This is a one-time notification. A large quantity generator may notify as part of the next Biennial Report. A small quantity generator must notify within 60 days of becoming subject to subpart P. Because large quantity generators are currently required to submit a Biennial Report, there is no cost or benefit associated with the provision for a large quantity generator to notify.

The EPA Regulatory Impact Analysis²⁹ estimates that the small quantity generator would incur a one-time notification cost of \$41.10 per facility. EPA's estimated that "these one-time costs are annualized over a 20-year period, assuming a 20-year gap between notifications."

Based on Hazardous Waste Section knowledge and experience the following costs are estimated for notification:

Since very small quantity generators will continue to operate under the existing requirements (40 CFR 262.14), they will not be required to notify.

Large quantity generator healthcare (private as well as federal, state and local government) and reverse distributors (private) will submit the notification of operating under subpart P when they submit the next biennial report so there is no additional cost associated with the requirement to notify. The 18 large quantity generators (15 private and 3 local government) who will renotify as small quantity generators cost is accounted for in Appendix B.

²⁹ EPA Regulatory Impact Analysis, page 57

Small quantity healthcare facilities (private as well as state, local, and federal government) will incur a one-time notification cost \$41.10 for each facility.

Based on Hazardous Waste Section knowledge and experience, it will take the Processing Assistant 30 minutes to process each notification.

Cost for Notification

Private Healthcare Facilities and Reverse Distributor:

- Large quantity generator and very small quantity generator facilities: 0
 - Small quantity generator facilities: 101 facilities x \$41.10 = \$4,151.10
- This is a one time cost that will occur in 2020. Fifteen facilities that are large quantity generators that can renotify as small quantity generators will also renotify at a cost of \$41.10 for each notification, but this is accounted for in Appendix B.

Federal Government Healthcare Facilities:

- Large quantity generator and very small quantity generator facilities: 0
 - Small quantity generator facilities: 1 facility x \$41.40 = \$41.40
- This is a one time cost that will occur in 2020.

State Government - Healthcare Facilities:

- Large quantity generator and very small quantity generator facilities: 0
 - Small quantity generator facilities: 3 facility x \$41.40 = \$123.30
- This is a one time cost that will occur in 2020.

State Government – Hazardous Waste Section

- 105 notifications will be processed x 0.5 hours = 52.5 hours x \$25/hour = \$1,312.50
- This is a one time cost that will occur in 2020. Eighteen facilities that are large quantity generators that can renotify as small quantity generators will also renotify at cost of \$225, but this is accounted for in Appendix B.

Local Government - Healthcare Facilities:

- Large quantity generator and very small quantity generator facilities: 0
- There will be 3 large quantity generators that will notify as small quantity generators in 2020, but this is accounted for in Appendix B.

Container Labeling:

Healthcare facilities operating under subpart P must label containers of non-creditable hazardous waste pharmaceuticals with the words "Hazardous Waste Pharmaceuticals." Currently, hazardous waste containers must be labeled with the words "Hazardous Waste" and an indication of the hazards of the contents of the containers. EPA's Regulatory Impact Analysis³⁰ estimates it takes 0.08 hours (5 minutes) of a technician's time to mark the labels with an indication of the hazards of the contents of the container. Also estimated are the annual cost of labeling per small quantity and large quantity generators. The difference between the baseline labeling requirements (current

³⁰ EPA's Regulatory Impact Analysis, page 74-75

requirements) and the labeling requirements under subpart P result in a cost savings of \$8.52 for each small quantity generator and \$8.51 for each large quantity generator. Table 22, in Appendix B on page 42 provides the wage growth rate estimated over time for labeling.

Benefits for Reduced Labeling Requirements:

Private Healthcare Facilities: $(116 \times \$8.52)(1 + \text{estimated wage growth for 2020 of } 1.67\%) = \1004.82

This is an annual benefit that starts in 2020. The number of facilities represented here does include the 15 facilities that renominated as a small quantity generator (from large quantity generator) when the rule was effective.

Federal Government Healthcare Facilities: $[(2 \text{ facilities} \times \$8.51) + (1 \text{ facility} \times \$8.52)] \times (1 + \text{estimated wage growth rate for 2020 of } 1.67\%) = \27.50

This is an annual benefit that starts in 2020.

State Government - Healthcare Facilities: $[(2 \text{ facilities} \times \$8.51) + (3 \text{ facilities} \times \$8.52)] \times (1 + \text{estimated wage growth rate for 2020 of } .99\%) = \43

This is an annual benefit that starts in 2020.

Local Government - Healthcare Facilities: $(3 \text{ facilities} \times \$8.52) \times (1 + \text{estimated wage growth rate for 2020 of } .99\%) = \25.81

This is an annual benefit that starts in 2020. The number of facilities represented here does include the 3 facilities that renominated as a small quantity generator (from large quantity generator) when the rule was effective.

Accumulation Time/Increase in Disposal:

Healthcare facilities operating under subpart P may accumulate non-creditable hazardous waste pharmaceuticals for up to one year. This is different than current hazardous waste generator requirements where a small quantity generator may accumulate hazardous waste on site for 180 days (or 270 days if the hazardous waste is transported 200 miles or more for disposal) and a large quantity generator may accumulate hazardous waste on site for 90 days. The increased amount of time allowed for accumulation along with the increase in hazardous waste pharmaceuticals that must be incinerated instead of sewerage may cause the healthcare facilities to accumulate more containers of hazardous waste for disposal. EPA's Regulatory Impact Analysis³¹ estimates that a small quantity generator hospital will have 1 additional 55-gallon container (drum) and a large quantity generator hospital will have 6 additional 55-gallon drums of hazardous waste pharmaceuticals a year at a cost of \$83 per container. Based on Table 22 in Appendix D on page 51 and an estimation that a 55-gallon container weighs on average 450 pounds, the Hazardous Waste Section agrees with the EPA's Regulatory Impact Analysis of one extra 55-gallon container of hazardous waste pharmaceuticals for a small quantity generator hospital/healthcare facility. The Hazardous Waste Section estimates that a large quantity generator hospital would only have 3 extra 55-gallon drums $(0.65 \text{ tons of hazardous waste pharmaceuticals} \times 2000 \text{ lbs./ton} = 1,300 \text{ lbs.} \div 450 \text{ lbs./drum} = 2.8 \text{ drums})$ and other healthcare facilities would only have 5 additional drums.

³¹ EPA's Regulatory Impact Analysis, page 58

EPA's Regulatory Impact Analysis³² estimates that the cost to transport a 55-gallon container to a hazardous waste treatment, storage, and disposal facility is \$47.52 per container. Based on the estimates in EPA's Regulatory Impact Analysis, a small quantity generator hospital would have an additional cost of \$130.52 a year. Based on the Hazardous Waste Section estimates, a large quantity generator hospital would have an additional cost of \$391.56 while a large quantity "other healthcare facility" would have an additional cost of \$652.60 a year due to the extra containers needed for accumulation of hazardous waste pharmaceuticals that had been sewerred in the past.

The Management Standards for Hazardous Waste Pharmaceuticals Rule creates a new standard for residues of hazardous waste pharmaceuticals in empty containers ("RCRA empty"). While the "RCRA empty" container provision was considered as part of EPA's Regulatory Impact Analysis as reducing the amount of hazardous waste, it was considered unquantified.

EPA's Regulatory Impact Analysis³³ states: "...healthcare facilities will now be able to consider containers that once held acute hazardous waste pharmaceuticals empty under RCRA regulations by removing the acute hazardous waste pharmaceutical. Previously, facilities generally had to triple rinse containers that once held acute hazardous waste or manage the residues in the containers as hazardous waste. EPA expects that this change will allow some healthcare facilities to generate and manage less waste that is considered hazardous waste and thus will experience a change in their generator category. However, there is inherent uncertainty surrounding the volume of acute hazardous waste generated by healthcare facilities that can be attributed to containers, and thus EPA was unable to quantify these potential cost savings."

Review of hazardous waste manifests from North Carolina hospitals indicate that hazardous waste is shipped off-site at least monthly (in some cases several times a month). Even with an extension in the amount of time that a facility is allowed to accumulate hazardous waste (one year instead of 180 days for small quantity generators or 90 days for a large quantity generator), space limitations at the hospital will require the hazardous waste pharmaceuticals to continue to be shipped off site as often as they currently are shipped. Even though the amount of hazardous waste pharmaceuticals that must be shipped off-site for incineration will increase due to the sewer prohibition, the Hazardous Waste Section believes the additional number of containers required for the additional hazardous waste pharmaceuticals that must be disposed of will be nominal compared to the amounts estimated in EPA's Regulatory Impact Analysis when the amount of hazardous waste pharmaceuticals that are considered RCRA empty containers are taken into consideration and removed from the equation. The cost to incinerate the additional hazardous waste pharmaceuticals instead of sewerred due to the sewer prohibition is discussed in Appendix D.

Overall, there is no cost or benefit associated with the increase in the amount of time to accumulate hazardous waste pharmaceuticals by healthcare facilities or by the increase in the number of containers needed to manage the additional hazardous waste pharmaceuticals that must be incinerated instead of sewerred.

³² EPA's Regulatory Impact Analysis, page 61

³³ EPA's Regulatory Impact Analysis, page 70

Additional Training:

Even though there is not a cost/benefit associated with the required on-site training to comply with the requirements of 40 CFR 266.502(b) in subsequent years, additional training will be necessary the first year the rule is effective to train facility staff of the new definitions, applicability, and requirements. EPA's Regulatory Impact Analysis³⁴ provides estimated total annual training costs both for facility personnel who handle hazardous waste and respond to hazardous waste emergencies and also awareness training for healthcare staff. The estimated costs for a small quantity generator to training 1 technician and 1 manager is \$1,727 per year. The estimated costs for a large quantity generator to train 4 technicians and 2 managers is \$3,581. The training cost includes 8 hours of training per employee describes plus the time to develop the training, any associated fees, and any associated administrative costs. EPA's Regulatory Impact Analysis also estimates the cost of awareness training that is necessary to provide to healthcare facility staff at \$1,540 per year. A retail facility cost of awareness training is \$25. All healthcare facilities will need to have both awareness training and the training specific to the personnel who handle hazardous waste and respond to emergencies. The following are the estimated costs associated with the additional training that will be needed the first year the rule is effective.

Cost for One-Time Additional Training

Private Healthcare Facilities and Reverse Distributor:

- Large quantity generator (all reverse distributors): $5 \times \$3,581 = \$17,905$
- Small quantity generator facilities (116 total facilities total with 54 hospitals and 62 retail facilities. The hospitals will need both specific and awareness training. The retail stores will need awareness training for facilities, but only six specific trainings since regional personnel represent many sites):
 $(54 \text{ hospitals} \times \$1,727) + (54 \times 1,540) + (62 \text{ retail facilities} \times \$25) + (6 \times 1,727) =$
 $\$188,330$

Total cost for private entities: \$206,235

This is a one time cost that will occur in 2020. The number of facilities represented here does include the 15 facilities that renotified as a small quantity generator (from large quantity generator) when the rule was effective.

Federal Government Healthcare Facilities:

- Large quantity generators: $(2 \times \$3,581) + (2 \times \$1,540) = \$10,242$
- Small quantity generator facilities (1 facility). The hospitals will need both specific and awareness training. $(1 \text{ hospital} \times \$1,727) + (1 \times 1,540) = \$3,267$

Total cost to federal government: \$13,509. This is a one time cost that will occur in 2020.

State Government Healthcare Facilities:

- Large quantity generators: $(2 \times \$3,581) + (2 \times \$1,540) = \$10,242$
- Small quantity generator facilities (3 facilities). The hospitals will need both specific and awareness training. $(3 \text{ hospital} \times \$1,727) + (3 \times 1,540) = \$9,801$

Total cost to state government: \$20,043. This is a one time cost that will occur in 2020.

³⁴ EPA's Regulatory Impact Analysis, page 72

Local Government Healthcare Facilities:

- Small quantity generator facilities (3 facilities). The hospitals will need both specific and awareness training. $(3 \text{ hospital} \times \$1,727) + (3 \times 1,540) = \$9,801$

This is a one time cost that will occur in 2020. The number of facilities represented here does include the 3 facilities that renotified as a small quantity generator (from large quantity generator) when the rule was effective.

DEA Exemption

The conditional exemption for hazardous waste pharmaceuticals that are also DEA controlled substances provides an exemption for five pharmaceuticals (chloral/chloral hydrate, fentanyl sublingual spray, phenobarbital, testosterone gels/solutions, valium injectable/gel). When these five pharmaceuticals are managed under the conditions of the exemption (specific DEA regulatory requirements for management and disposal), they are exempt from RCRA hazardous waste requirements. This exemption is not effective until authorized states adopt the provision.

Prior to the sewer prohibition effective date (August 21, 2019), hazardous waste pharmaceuticals that are also DEA controlled substances were sewered for disposal (meeting both RCRA and DEA disposal requirements). Now that the RCRA sewer prohibition is effective, this waste stream is no longer allowed to be sewered. Until the DEA exemption is effective, this waste stream is subject to full hazardous waste regulation and DEA requirements. Disposal of hazardous waste pharmaceuticals that are also DEA controlled substances is expensive. North Carolina healthcare facilities that operate as a large quantity generator of hazardous waste estimate that the disposal is between \$3,500 to \$5,000 per shipment and that at least one shipment must be made a year for this waste stream. North Carolina healthcare facilities also indicated that the disposal unit used to meet DEA requirements to accumulate hazardous waste pharmaceuticals is approximately \$350 a unit and to arrange for the service for disposal. For purposes of this document, an average of the disposal cost is used (\$4,250 per year) and added to one unit used for accumulation (\$350). An estimated cost of \$4,600 per year is used as the cost for a healthcare facility to dispose of hazardous waste pharmaceuticals that are also DEA controlled substances until the DEA exemption is effective.

As mentioned above, there are five hazardous waste pharmaceuticals that are also DEA controlled substances. North Carolina healthcare facilities indicated that typically only 2-3 of these subject pharmaceuticals are actually dispensed at the facility and the use at the facility is sporadic. Additionally, when the pharmaceuticals are dispensed, most often they are used entirely for their intended purpose so there is no associated waste. North Carolina healthcare facilities indicated that only about 5% of the time there is associated waste that must be managed for disposal. Due to the very small amount of this type of waste, only the large quantity generator healthcare facilities will generate enough to necessitate a shipment of this waste in the 11 months until the DEA exemption is effective.

Once the DEA exemption is effective, the large quantity generator facilities will receive the benefit of no longer having to manage this waste stream under RCRA hazardous waste requirements (as long as DEA requirements are met).

Cost for Managing/Disposal of HW Pharmaceuticals that are DEA Controlled Substances

Private Healthcare Facilities:

- Cost for 2019: 15 facilities x \$4,600 = \$69,000 x 5 months (=0.42) = \$28,980
- Cost for 2020: 15 facilities x \$4,600 = \$69,000 x 6 months (=0.5) = \$34,500

This is a one time cost that will occur in 2019 and 2020 until the DEA exemption is effective.

Federal Government Healthcare Facilities:

- Cost for 2019: 2 facilities x \$4,600 = \$9,200 x 0.42 = \$3,864
- Cost for 2020: 2 facilities x \$4,600 = \$9,200 x 0.5 = \$4,600

This is a one time cost that will occur in 2019 and 2020.

State Government Healthcare Facilities:

- Cost for 2019: 2 facilities x \$4,600 = \$9,200 x 0.42 = \$3,864
- Cost for 2020: 2 facilities x \$4,600 = \$9,200 x 0.5 = \$4,600

This is a one time cost that will occur in 2019 and 2020.

Local Government Healthcare Facilities:

- Cost for 2019: 3 facilities x \$4,600 = \$13,800 x 0.42 = \$5,796
- Cost for 2020: 3 facilities x \$4,600 = \$13,800 x 0.5 = \$6,900

This is a one time cost that will occur in 2019 and 2020.

Benefits from the DEA exemption:

Private Healthcare Facilities:

- Benefits for 2020: 15 facilities x \$4,600 = \$69,000 x 6 months (=0.5) = \$34,500
- Annual benefit starting in 2021: 15 facilities x \$4,600 = \$69,000

Federal Government Facilities:

- Benefits for 2020: 2 facilities x \$4,600 = \$9,200 x 6 months (=0.5) = \$4,600
- Annual benefit starting in 2021: 2 facilities x \$4,600 = \$9,200

State Government Facilities:

- Benefits for 2020: 2 facilities x \$4,600 = \$9,200 x 6 months (=0.5) = \$4,600
- Annual benefit starting in 2021: 2 facilities x \$4,600 = \$9,200

Local Government Facilities:

- Benefits for 2020: 3 facilities x \$4,600 = \$13,800 x 6 months (=0.5) = \$6,900
- Annual benefit starting in 2021: 3 facilities x \$4,600 = \$13,800

Appendix D

Sewer Prohibition

The Management Standards for Hazardous Waste Pharmaceuticals Rule prohibits the discharge of hazardous waste pharmaceuticals to the sewer system that passes through to a publicly-owned treatment works. Healthcare facilities (including very small quantity generators) and reverse distributors are subject to this prohibition. This provision went into effect nationwide on August 21, 2019 and EPA will administer/enforce the requirement until authorized states adopt the provision.

Prior to the new provisions, healthcare facilities and reverse distributors were allowed to sewer hazardous waste pharmaceuticals. Retail pharmacies indicated that they did not sewer hazardous waste pharmaceuticals even when allowed. EPA's Regulatory Impact Analysis³⁵ also stated, "because retail facilities do not normally administer medications to patients, this RIA assumes that no hazardous waste pharmaceuticals generated by these facilities are sewered in the baseline."

EPA's Regulatory Impact Analysis³⁶ provides key assumptions as far as how non-creditable and potentially creditable hazardous waste pharmaceuticals were managed by different facility types (reverse distributors, hospitals, healthcare facilities, retail facilities and long-term care facilities) prior to the sewer prohibition (baseline). These key assumptions are described below.

Reverse distributors:

Although a significant portion of the hazardous waste pharmaceuticals sent to a reverse distributor are subsequently sent to another reverse distributor for additional verification for manufacturer credit, the EPA Regulatory Impact Analysis assumes that these wastes are ultimately managed through hazardous waste incineration.

Small quantity generator and large quantity generator hospitals and other healthcare facilities (excluding retail facilities):

- Potentially creditable hazardous waste pharmaceuticals generated by small and large quantity generator hospitals and healthcare facilities are assumed to be sent to a reverse distributor and subsequently incinerated.
- For non-creditable hazardous waste pharmaceuticals generated by these facilities, the EPA RIA assumes that some percentage is sewered after facilities notify their local wastewater treatment plant, while the remainder is incinerated. EPA's Regulatory Impact Analysis estimated the following percentage is sewered³⁷:
 - 14% for SQGs and LQG hospitals;
 - 17% for SQG other healthcare facilities and 21% for LQG other healthcare facilities

³⁵ EPA's Regulatory Impact Analysis, page 50

³⁶ EPA's Regulatory Impact Analysis, page 49-50

³⁷ EPA's Regulatory Impact Analysis, page 64

Very small quantity generator hospitals and other healthcare facilities (excluding retail facilities):

- Similar to small and large quantity generator hospitals and healthcare facilities, potentially creditable hazardous waste pharmaceuticals generated by very small quantity generator healthcare facilities are assumed to be sent to a reverse distributor and subsequently incinerated.
- Non-creditable hazardous waste pharmaceuticals generated by very small quantity generator healthcare facilities are split between three management methods in EPA's Regulatory Impact Analysis:
 - Sewering with notification [18% for hospitals and 21% for other healthcare facilities³⁸],
 - MSW disposal [North Carolina Solid Waste Rules prohibit both hazardous waste and liquid waste in North Carolina landfills, so this is not an option for disposal in North Carolina.] and
 - Incineration [All remaining patient care hazardous waste pharmaceuticals generated by very small quantity generators are assumed to be incinerated.]

Small quantity and large quantity generator retail facilities:

- Potentially creditable hazardous waste pharmaceuticals generated by small and large quantity retail facilities are assumed to be sent to a reverse distributor and subsequently incinerated.
- Non-creditable hazardous waste pharmaceuticals generated by these facilities are assumed to be incinerated.

Very small quantity generator retail facilities:

- Potentially creditable hazardous waste pharmaceuticals generated by very small quantity generator healthcare facilities are assumed to be sent to a reverse distributor and subsequently incinerated.
- EPA's Regulatory Impact Analysis assumed non-creditable hazardous waste pharmaceuticals generated by very small quantity generator healthcare facilities were split between two management methods: municipal solid waste disposal and incineration. Since North Carolina does not allow hazardous waste (even from a very small quantity generator to be disposed in the landfill), the non-creditable hazardous waste pharmaceuticals generated by very small quantity generators is assumed to be incinerated. EPA's Regulatory Impact Analysis also stated, "because retail facilities do not normally administer medications to patients, this RIA assumes that no hazardous waste pharmaceuticals generated by these facilities are sewered in the baseline."

Very small quantity and small quantity generator long-term care facilities: Prior to the sewer prohibition, patient waste at nursing care facilities and continuing care retirement communities was considered household hazardous waste and therefore was not subject to RCRA hazardous waste regulation.

EPA's Regulatory Impact Analysis³⁹ states "The costs of hazardous waste incineration is approximately \$2.26 per pound.... The cost of sewerage, excluding notification, is an estimated

³⁸ EPA's Regulatory Impact Analysis, page 64

³⁹ EPA's Regulatory Impact Analysis, pages 61-62

\$4.09 per 1,000 gallons. To convert this sewerage cost to an estimated cost per ton (\$1.06 per ton), this RIA assumes that sewerage pharmaceuticals have the same density as water (8.34 pounds per gallon). The cost of notifying POTWs is assumed to be similar to the cost of RCRA notification to EPA. As indicated in the notification section above, this cost is \$57.29 per facility. This translates to an annualized cost of \$5.41 over 20 years."

EPA's Regulatory Impact Analysis indicates that only hospitals, other healthcare facilities and long-term care facilities were utilizing the sewer disposal option prior to the prohibition. Table 24, on page 56 provides the annual cost to incinerate hazardous waste pharmaceuticals instead of sewer dispose them. The annual cost per ton to sewer hazardous waste pharmaceuticals is so low (e.g. the annual cost of a large quantity generator hospital to sewer hazardous waste pharmaceuticals is \$0.68) that it is not deducted from the cost to incinerate to determine the differential between incineration and sewerage. The one-time notification to the publicly owned treatment works (which EPA's Regulatory Impact Analysis⁴⁰ estimates at \$57.29 per facility) is also not factored in as a one-time cost or benefit for because the notification already occurred.

Review of the type of facilities that have notified in the RCRAInfo database indicates the facilities are either hospitals or retail pharmacies. Since the retail pharmacies are not sewerage hazardous waste pharmaceuticals, only the values to incinerate hazardous waste pharmaceuticals (column 7 in Table 24) for hospitals were ultimately used in the cost/benefit analysis. The values for other healthcare facilities and long-term care facilities were provided in Table 24 for reference and comparison. There is an assumption made that the healthcare facilities and reverse distributors will operate in compliance with the sewer prohibition. Uncertainty surrounds the estimates of hazardous waste pharmaceuticals that were sewerage in the past and whether other healthcare facilities and long-term care facilities are in compliance with the notification requirements. There may be other healthcare facilities/long-term care facilities that are operating as a small or large quantity generator of hazardous waste that should have notified as a hazardous waste generator but did not notify. The overall costs associated with the sewer prohibition would increase if any facilities currently not accounted for in the RCRAInfo were to notify. The overall benefits to human health and the environment would also increase if other healthcare facilities that are not currently captured in this Regulatory Impact Analysis were to notify.

⁴⁰ EPA's Regulatory Impact Analysis, page 62

Table 24

Annual Cost to Incinerate Hazardous Waste (HW) Pharmaceuticals (Pharm) Instead of Sewer Dispose						
1	2	3	4	5	6	7
Generator Category	Type of Facility	Estimated Mean Annual HW Pharm Generated per Facility Basis (tons) *	Percentage of Total HW Pharm Sewered **	Estimated Amount HW Pharm (tons) Sewered ****	Annual Cost to Sewer HW Pharm (\$1.06 per ton) *****	Annual Cost to Incinerate HW Pharm Instead of Sewer (\$2.26 per pound) *****
LQG	Hospital	4.62	14%	0.65	\$0.68	\$2,938
	Other Healthcare Facility	5.48	21%	1.15	\$1.22	\$5,198
	Long-term Care	2.23	21%	0.47	\$0.50	\$2,124
SQG	Hospital	0.95	14%	0.13	\$0.14	\$588
	Other Healthcare Facility	1.33	17%	0.23	\$0.24	\$1,040
	Long-term Care	3.00	21%	0.63	\$0.67	\$2,848
VSQG	Hospital	0.065	18%	0.01	\$0.01	\$45
	Other Healthcare Facility	0.092	21%	0.02	\$0.02	\$90
	Long-term Care	0.0207	21%	0.004	\$0.006	\$18

* The estimated mean annual hazardous waste pharmaceuticals is provided in the EPA's RIA, page 44.

**The percentage sewered is provided in EPA's Regulatory Impact Analysis, page 64.

***Estimated amount HW Pharmaceuticals sewered in tons (column 5) = (column 3) x (column 4).

****EPA's RIA, page 61-62 estimates the cost to sewer is \$1.06 per ton.

***** EPA's RIA, page 61-62 estimates the cost to incinerate HW Pharmaceuticals is \$2.26 per pound. Annual Cost to Incinerate HW Pharmaceuticals Instead of Sewer (column 10) = (column 5 x 2000) x 2.26.

Appendix E

Development of Cost Estimates for Hazardous Waste Section Inspections, Complaints, Notices of Violation and Compliance Assistance Visits

The new requirements of the Management Standards for Hazardous Waste Pharmaceuticals Rule will initially increase the time for hazardous waste inspectors to complete hazardous waste inspections and complaint investigations. The increased amount of time spent on inspections and complaint investigations will only span for the first three years the rule is effective.

Based on Hazardous Waste Section data and knowledge of the hazardous waste generator operations at these facilities, Hazardous Waste Section staff estimate that three extra hours (one extra hour spent at a facility during an inspection or complaint investigation, one extra hour will be spent on the report written after a site visit, and one extra hour will be spent on writing a Notice of Violation due to the change in rule citations) will need to be spent on inspections and complaints involving the new provisions of the Management Standards for Hazardous Waste Pharmaceuticals Rule.

The Hazardous Waste Section receives complaints concerning facilities operating out of compliance with the rules from facility employees, other government agencies, neighbors of the facility and the media. Based on historical data on the types of complaints and numbers of facilities involved in complaints, it is assumed that there will be 1 complaint per year of facilities involving the provisions of this rule for the first three years the rule is effective. The following estimates are based on the proportions of type of facility (private versus federal, state, and local government) to the total number of hazardous waste generators. It is estimated that the 3 future complaint investigations conducted annually will be at private sector healthcare facilities or reverse distributors. Based on historical Hazardous Waste Section information, 50% of complaints receive a Notice of Violation. Based on the proportions of type of facility to the total number of hazardous waste generators, private sector hazardous waste generators are estimated to receive the 5 Notices of Violations. Based on Hazardous Waste Section knowledge and experience, receipt of a Notice of Violation will cause the hazardous waste generator, on average, 2 hours of work to remedy any issues and respond to the Notice of Violation.

Over the past 5 years, the Hazardous Waste Section conducted an average of 480 inspections of hazardous waste generator facilities per year. The following estimates are based on the proportions of type of healthcare facility/reverse distributor (private versus federal, state, and local government) to the total number of hazardous waste generators. It is assumed that of the 480 future inspections conducted annually, 36 will be private sector healthcare facilities/reverse distributors. A state government healthcare facility will be inspected every other year. Federal and local government healthcare facilities will not get inspected based solely on the proportion assumption. Based on historical Hazardous Waste Section information, only about 10% of the inspections will result in a Notice of Violation. Based on the proportions of type of healthcare/reverse distributor to the total number of hazardous waste generators, the 4 Notices of Violations are estimated to be distributed only to private sector healthcare facilities/reverse distributors. Based on Hazardous Waste Section knowledge and experience, receipt of a Notice

of Violation will cause the hazardous waste generator, on average, 2 hours of work to remedy any issues and respond to the Notice of Violation.

Over the past 5 years, the Hazardous Waste Section conducted an average of 71 Compliance Assistance Visits at hazardous waste generator sites. The following estimates are based on the proportions of type of healthcare facility/reverse distributor (private versus federal, state, and local government) to the total number of hazardous waste generators. It is assumed that of the 71 future Compliance Assistance Visits, that 5 will be at private sector healthcare facilities/reverse distributors. Based on Hazardous Waste Section knowledge and experience, a Compliance Assistance Visit takes on average 4 hours.

Table 25, below, summarizes the forecast for the number of complaints, inspections, Notices of Violation, and Compliance Assistance Visits by type of healthcare facility/reverse distributor per year.

Table 25

Forecast for the Number of Complaints, Inspections, Notices of Violation (NOV)s and Compliance Assistance Visits per Year at Healthcare Facilities and Reverse Distributors							
	Proportion of Total Number of Healthcare/Reverse Distributors	Proportion of Healthcare Facilities/Reverse Distributors to Total Number of Generators (Healthcare/Reverse Distributors to total generators)	Estimated Number of Complaints at Healthcare Facilities/Reverse Distributors (per year)	Estimated Number of Complaints Receiving NOVs – 50% of the Complaints (per year)	Estimated Number of Inspections of Healthcare Facilities and Reverse Distributors (per year)	Estimated Number of Inspections Receiving NOVs – 10% of the Inspections (per year)	Estimated Number of Compliance Assistance Visits (per year)
Private Sector	97.4%	553 / 7,448=7.4%	1	.5 (or 1 every other year)	36	4	5
Federal Government	0.9%	5 / 7,448 = .067%	0	0	0	0	0
State Government	1.2%	7 / 7,448 = .093%	0	0	.5 (or 1 every other year)	0	0
Local Government	0.5%	3 / 7,448 = .040%	0	0	0	0	0
Total	100%	---	1	.5 (or every other year)	36.5	4	5

The Hazardous Waste Section acknowledges that inspections, complaints, Notices of Violation, and requests for Compliance Assistance Visits are not necessarily predictable and will not always fall into the proportions for type of facility described. However, using the proportions of the type of healthcare facility/reverse distributor to the total number of hazardous waste generators is the best way to predict the number of complaints, inspections, Notices of Violations, and Compliance Assistance Visits for each type of facility since there is not any historical information for

inspections, complaints, Notices of Violation and Compliance Assistance Visits based on type of facility.

The loaded hourly wages shown below and used in the cost and benefit summaries have been adjusted for inflation. Additional inflation adjusted hourly wage information can be found in Appendix A. It is assumed that the Hazardous Waste Section Inspector will be performing the complaint investigation or inspection and issuing the Notice of Violation and the Environmental Specialist will be the hazardous waste generator personnel involved with the inspection, complaint, and/or Compliance Assistance Visit and respond to a Notice of Violation.

Examples of how the costs are calculated are below.

Cost to Private Sector Healthcare Facility/Reverse Distributor:

- Complaints: (1 complaints x 2 additional hours) + (.5 Notices of Violation x 2 hours) = 3 hours
- Inspections: (36 inspections x 2 additional hours) + (4 Notices of Violation x 2 hours) = 80 hours
- Compliance Assistance Visits (5 CAVs x 4 hours) = 20 hours

Total estimated extra time spent on Complaints, Inspections, Compliance Assistance: (3 hours for Complaints + 80 hours for Inspections + 20 hours for CAVs) = 103 hours x \$45/hour = \$4,635

This will be an annual cost for the first three years starting in 2020.

Cost to State Government Healthcare Facility:

- Inspections: (.5 inspection x 2 additional hours) = 1 hours

Total estimated extra time spent on Inspections: (1 hours for Inspections) = 1 hour x \$45/hour = \$45

This will be an annual cost occurring every year for three years starting in 2020.

Costs to the Hazardous Waste Section (State Government):

- The estimated total number of extra hours spent on complaints: 1 complaint/year involving Management Standards for Hazardous Waste Pharmaceuticals Rule provisions x 2 additional hours due to the new provisions = 2 extra hours x \$40/hour = \$80
- The estimated extra time spent on Notices of Violation issued from a complaint investigation: 1 complaint/year x .50 for the number of complaints resulting in a Notice of Violation = .5 complaint receiving Notices of Violation x 1 additional hour spent on each Notice of Violation = .5 hours x \$40/hour = \$20
- The estimated number of extra hours spent on inspections: 36 inspections/year involving Management Standards for Hazardous Waste Pharmaceuticals Rule x 2 additional hours due to the new provisions = 72 hours x \$40/hour = \$2,880
- The estimated extra time spent on Notices of Violation issued from an inspection: 36 inspections/year x .10 for the number of inspections resulting in a Notice of Violation = 3.6 (round up to 4) inspections receiving Notices of Violation x 1 additional hour spent on each Notice of Violation = 4 hours x \$40/hour = \$160

- The estimated time spent on Compliance Assistance Visit: 4 hours/visit x 5 CAVs = 20 hours x \$40/hour = \$800

Total estimated cost of extra hours spent on inspections, complaints, and Compliance Assistance Visits by the Hazardous Waste Section: (2 hours for complaints + 72 hours for inspections + 4.5 hours for Notices of Violation and 20 hours Compliance Assistance Visits) = 98.5 hours x \$40/hour = \$3,940. This will be an annual cost for the first three years starting in 2020.

Appendix F

Development of Cost/Benefit Estimates for Enforcement

Informal enforcement actions (Notice of Violation) are already accounted for in the Development of Cost Estimates for Inspections, Complaints, and Compliance Assistance Visits section, so this section focuses on enforcement actions that result in a penalty.

The average of the Inspection and Investigation costs from enforcements for FY15 to FY19 (five years) is \$2,189.

When divided by the average cost per hour spent on enforcements, the result shows the average number of hours spent on enforcements by staff other than the compliance order writer (i.e. Inspector, Chemist, Branch Head, Section Chief, Administrative staff).

$$\$2,189 \div \$39.00/\text{hour} = 56 \text{ hours}$$

Based on an average of the past four compliance orders, the compliance order writer spends an average of 89.25 hours on a compliance order. This was rounded down to 89 hours.

Total time spent on a compliance order: 56 hours + 89 hours: 145 hours

Over the past five years the average number of enforcement cases per year was 5. The average total penalty assessed to the facilities receiving compliance orders over the past five years was: \$34,147. The facilities receiving compliance orders over the past five years were all private facilities. In the period of 2003 to 2019, two compliance orders (out of a total of 124) were assessed to state government facilities and it occurred prior to 2014.

The new provisions of the Management Standards for Hazardous Waste Pharmaceuticals Rule will be complicated and unfamiliar to the regulated entities. Based on Hazardous Waste Section review of enforcement history, Hazardous Waste Section staff estimate that there will be enforcement cases involving the new provisions of the Management Standards for Hazardous Waste Pharmaceuticals Rule. Due to the Hazardous Waste Section efforts to provide education and outreach and because some of the instances will be addressed through issuing a Notice of Violation (see Appendix E), Hazardous Waste Section staff estimate that there will be 1 additional enforcement case related to this new rule within five years of the rule becoming effective. For purposes of this analysis, an assumption is made that one enforcement will occur in 2023. Based on the historical enforcement data tracked by the Hazardous Waste Section, it is assumed this future compliance orders will be issued to private sector. This assumption is made based on the proportion of private sector hazardous waste generators that are healthcare facilities/reverse distributors making up 97.4% of the total number of hazardous waste generators that are healthcare facilities/reverse distributors. For the period of 2003 to 2019, only 1.6% of the compliance orders were issued to facilities that were not private sector. Proportionally, only 0.032 of a compliance order would be issued to entities that are not private sector. Since this number is so low, the enforcement cost is estimated only for private sector. Based on Hazardous Waste Section

knowledge and experience, receipt of a compliance order will cause the hazardous waste generator, on average, 10 hours of work to remedy any issues and respond to the compliance order. The county school system (local government) receives the penalty payments from the compliance order.

The loaded hourly wages shown below and used in the cost and benefit summaries have been adjusted for inflation. Additional inflation adjusted hourly wage information can be found in Appendix A. Since many different Hazardous Waste Section spend time on development, administration, and follow-up on compliance orders, the Hazardous Waste Section staff average salary is used. It is assumed that the Environmental Specialist will be the personnel who responds to the compliance order for the healthcare facility/reverse distributor.

Cost to Private Sector:

Total estimated cost for enforcements assessed to private sector: 1 enforcement per year at \$34,147. This is a one time cost occurring in 2023.

Total estimated time spent on the enforcement:

1 enforcement (in 2023) x 10 hours x \$48 hour = \$480.

Cost to the Hazardous Waste Section (State Government):

The total time spent on enforcements per year is estimated to be (145 hours x 1 additional compliance order) resulting in 145 hours/year at a cost of \$42/hour.

Total estimated cost for one enforcement (in 2023): \$6,090.

Benefit to the County School System (Local Government):

The school system in the county where the penalty was assessed on the hazardous waste generator will receive the compliance order penalty payment. This is an on-time benefit of \$34,147 in 2023.

Appendix G

Development of Cost Estimate for Hazardous Waste Section for Education and Outreach

To effectively implement the provisions of the Management Standards for Hazardous Waste Pharmaceuticals Rule and to adequately inform regulated entities, the Hazardous Waste Section will need to offer educational and informational materials that will require the time of staff. Hazardous Waste Section cost estimates are based on previous experience related to educating regulated facilities and providing them with information about new and/or updated regulations. The cost estimates for the additional education and outreach for the Management Standards for Hazardous Waste Pharmaceuticals Rule are described below:

	HOURS	TOTAL
Development of Educational Materials:		
- Guidance Documents/ Fact sheets		
~ Summarizing Rule	8	
~ Writing and Proofing	16	
- PowerPoint for Presentation	16	
		40
Web Page:		
- Summarize and collect documents	16	
- Format and add to existing web page	16	
		32
Presentations:		
- Preparation and Practice	20	
- Presentations (5/year)	40	
		60
Total:		132

The loaded hourly wages shown below and used in the cost and benefit summaries have been adjusted for inflation. Additional inflation adjusted hourly wage information can be found in Appendix A.

Cost to the Hazardous Waste Section (State Government):

The additional 132 hours of staff time for education and outreach at the average cost of \$40/hour results in a cost to Hazardous Waste Section of \$5,280. This will be a one-time cost for 2020. Costs for presentations (60 hours per year) will recur annually thereafter.

Appendix H

Development of Cost Estimate for Hazardous Waste Section Training

Hazardous Waste Section staff will require additional training to be able to provide technical assistance and conduct compliance inspections implementing the provisions of the Management Standards for Hazardous Waste Pharmaceuticals Rule. Some of the Hazardous Waste Section staff will only need a brief overview of the new provisions while others will need a more comprehensive overview. Below are the estimated hours for each type of overview and an estimated average of hours for Hazardous Waste Section training.

Brief Overview: 1 hour of training

Description of Training: Focused on how the new rule provisions will affect: 1) permitted hazardous waste facilities overseen by the Facilities Management Branch of the Hazardous Waste Section and 2) notifications of subpart P activity by healthcare facilities/reverse distributors that are overseen by the Financial and Information Management Unit of the Hazardous Waste Section
Number of Hazardous Waste Section staff to receive this type of training: 18

Total hours of training: 18

Comprehensive Overview: 4 hours of training

Description of Training: Focused on the specifics of the new rule provisions to be able to conduct an inspection on facilities implementing the provisions of the new rule.
Number of Hazardous Waste Section staff to receive this type of training: 23

Total hours of training: 92

Development, preparation, and review of the training material: 25 hours

This information will have a different scope than the educational material prepared for the regulated entities as part of the Education and Outreach Cost in Appendix G.

The loaded hourly wages shown below and used in the cost and benefit summaries have been adjusted for inflation. Additional inflation adjusted hourly wage information can be found in Appendix A.

Cost to the Hazardous Waste Section (State Government):

The Hazardous Waste Section spend a total of 135 hours on training at an average cost of \$39/hour for a total cost of \$5,265. This will be a one-time cost for the year prior to the rule's effective date (2019). Training costs, less the training material development costs (20 hours), will also be incurred for the year the rule is effective (2020).

Appendix I

Summary of Costs and Benefits to Private Sector and Federal, State, & Local Government

Summary of Cost and Benefits for Private Sector

Private Sector Healthcare Facilities and Reverse Distributors Cost and Benefits Overview											
Year	0	1	2	3	4	5	6	7	8	9	10
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
COSTS											
Sewer Prohibition	\$29,067	\$51,582	\$33,957	\$33,957	\$33,957	\$33,957	\$33,957	\$33,957	\$33,957	\$33,957	\$33,957
Training		\$206,235									
Notification		\$4,768									
Additional Time (Inspection, Complaints, Compliance Assistance)		\$4,635	\$4,738	\$4,841							
Enforcement (Penalties)					\$34,627						
DEA Pharmaceutical (Management/Disposal)	\$28,980	\$34,500									
Total Costs	\$58,047	\$301,720	\$38,695	\$38,798	\$68,584	\$33,957	\$33,957	\$33,957	\$33,957	\$33,957	\$33,957
BENEFITS											
Reduction In Fees		\$18,375	\$18,375	\$18,375	\$18,375	\$18,375	\$18,375	\$18,375	\$18,375	\$18,375	\$18,375
Not having to meet Large Quantity Generator Requirements		\$51,139	\$51,610	\$59,302	\$52,228	\$60,243	\$52,920	\$61,262	\$53,451	\$62,476	\$54,357
Labeling		\$502	\$1,026	\$1,049	\$1,072	\$1,095	\$1,122	\$1,148	\$1,174	\$1,200	\$1,227
RCRA Empty Containers		Unquantified									
DEA Exemption		\$34,500	\$69,000	\$69,000	\$69,000	\$69,000	\$69,000	\$69,000	\$69,000	\$69,000	\$69,000
Total Benefits		\$104,516	\$140,011	\$147,725	\$140,675	\$148,713	\$141,417	\$149,785	\$141,999	\$151,051	\$142,959
Net Impact	-\$58,047	-\$197,203	\$101,316	\$108,927	\$72,091	\$114,756	\$107,460	\$115,828	\$108,042	\$117,094	\$109,002
The 11-year NPV of Impact is \$397,600.											

Summary of Cost and Benefits for Federal Government

Federal Healthcare Facilities Cost and Benefits Overview											
Year	0	1	2	3	4	5	6	7	8	9	10
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
COSTS											
Sewer Prohibition	\$2,753	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554
Training		\$13,509									
Notification		\$41									
DEA Pharmaceutical (Management/Disposal)	\$3,864	\$4,600									
Total Costs	\$6,617	\$24,704	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554	\$6,554
BENEFITS											
Labeling		\$14	\$28	\$29	\$29	\$30	\$31	\$32	\$32	\$33	\$34
RCRA Empty Containers		Unquantified									
DEA Exemption		\$4,600	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200
Total Benefits		\$4,614	\$9,228	\$9,229	\$9,229	\$9,230	\$9,231	\$9,232	\$9,232	\$9,233	\$9,234
Net Impact	-\$6,617	-\$20,090	\$2,674	\$2,675	\$2,675	\$2,676	\$2,677	\$2,678	\$2,678	\$2,679	\$2,680
The 11-year NPV of Impact is \$-9,095.											

Summary of Cost and Benefits for State Government

State Government Cost and Benefits Overview											
Year	0	1	2	3	4	5	6	7	8	9	10
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
COSTS											
State Government - Healthcare Facility											
Sewer Prohibition	\$3,247	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730
Training		\$20,043									
Notification		\$123									
Additional Time (Inspection, Complaints, Compliance Assistance)		\$45	\$46	\$47							
DEA Pharmaceutical (Management/Disposal)	\$3,864	\$4,600									
State Government - Hazardous Waste Section											
Notification		\$1,538									
Training/Outreach (External)		\$5,280	\$2,400	\$2,460	\$2,520	\$2,520					
Training (Internal)	\$5,265	\$4,600									
Additional Time (Inspection, Complaints, Compliance Assistance)		\$3,940	\$3,940	\$4,039							
Enforcement					\$6,090						
Reduction In Fees		\$22,050	\$22,050	\$22,050	\$22,050	\$22,050	\$22,050	\$22,050	\$22,050	\$22,050	\$22,050
Total Costs	\$12,376	\$69,949	\$36,166	\$36,326	\$38,390	\$32,300	\$29,780	\$29,780	\$29,780	\$29,780	\$29,780
BENEFITS											
State Government - Healthcare Facility											
RCRA Empty Containers		Unquantified									
Labeling		\$22	\$45	\$46	\$47	\$47	\$48	\$49	\$49	\$50	\$51
DEA Exemption		\$4,600	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200
Total Benefits		\$4,622	\$9,245	\$9,246	\$9,247	\$9,247	\$9,248	\$9,249	\$9,249	\$9,250	\$9,251
Net Impact	-\$12,376	-\$65,327	-\$26,921	-\$27,080	-\$29,143	-\$23,053	-\$20,532	-\$20,531	-\$20,531	-\$20,530	-\$20,529
The 11-year NPV of Impact is -\$217,736.											

Summary of Cost and Benefits for State Government – Healthcare Facilities

State Government - Healthcare Facility Cost and Benefits Overview											
Year	0	1	2	3	4	5	6	7	8	9	10
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
COSTS											
State Government - Healthcare Facility											
Sewer Prohibition	\$3,247	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730
Training		\$20,043									
Notification		\$123									
Additional Time (Inspection, Complaints, Compliance Assistance)		\$45	\$46	\$47							
DEA Pharmaceutical (Management/Disposal)	\$3,864	\$4,600									
Total Costs	\$7,111	\$32,541	\$7,776	\$7,777	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730	\$7,730
BENEFITS											
State Government - Healthcare Facility											
RCRA Empty Containers	Unquantified										
Labeling		\$22	\$45	\$46	\$47	\$47	\$48	\$49	\$49	\$50	\$51
DEA Exemption		\$4,600	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200	\$9,200
Total Benefits		\$4,622	\$9,245	\$9,246	\$9,247	\$9,247	\$9,248	\$9,249	\$9,249	\$9,250	\$9,251
Net Impact	-\$7,111	-\$27,919	\$1,469	\$1,469	\$1,517	\$1,517	\$1,518	\$1,519	\$1,519	\$1,520	\$1,521
The 11-year NPV of Impact is -\$24,041.											

Summary of Cost and Benefits for State Government – Hazardous Waste Section

State Government - Hazardous Waste Section Cost and Benefits Overview											
Year	0	1	2	3	4	5	6	7	8	9	10
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
COSTS											
State Government - Hazardous Waste Section											
Notification		\$1,538									
Training/Outreach (External)		\$5,280	\$2,400	\$2,460	\$2,520	\$2,520					
Training (Internal)	\$5,265	\$4,600									
Inspections, Complaints, Compliance Assistance		\$3,940	\$3,940	\$4,039							
Enforcement					\$6,090						
Reduction In Fees		\$22,050	\$22,050	\$22,050	\$22,050	\$22,050	\$22,050	\$22,050	\$22,050	\$22,050	\$22,050
Total Costs	\$5,265	\$37,408	\$28,390	\$28,549	\$30,660	\$24,570	\$22,050	\$22,050	\$22,050	\$22,050	\$22,050
BENEFITS											
State Government - Hazardous Waste Section											
Total Benefits		\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Net Impact	-\$5,265	-\$37,408	-\$28,390	-\$28,549	-\$30,660	-\$24,570	-\$22,050	-\$22,050	-\$22,050	-\$22,050	-\$22,050
The 11-year NPV of Impact is -\$193,695.											

Summary of Costs and Benefits to Local Government

Local Healthcare Facilities Cost and Benefits Overview											
Year	0	1	2	3	4	5	6	7	8	9	10
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
COSTS											
Sewer Prohibition	\$3,702	\$5,289	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764
Training		\$9,801									
Notification		\$123									
DEA Pharmaceutical (Management/Disposal)	\$5,796	\$6,900									
Total Costs	\$9,498	\$22,113	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764	\$1,764
BENEFITS											
Reduction In Fees		\$3,675	\$3,675	\$3,675	\$3,675	\$3,675	\$3,675	\$3,675	\$3,675	\$3,675	\$3,675
Not having to meet Large Quantity Generator Requirements		\$10,177	\$10,268	\$11,807	\$10,393	\$11,969	\$10,516	\$12,143	\$10,635	\$12,372	\$10,826
Labeling		\$13	\$26	\$27	\$27	\$27	\$28	\$28	\$29	\$29	\$29
RCRA Empty Containers		Unquantified									
DEA Exemption		\$6,900	\$13,800	\$13,800	\$13,800	\$13,800	\$13,800	\$13,800	\$13,800	\$13,800	\$13,800
Enforcement (Penalty Received by School System)					\$34,147						
Total Benefits		\$20,765	\$27,769	\$29,309	\$62,042	\$29,472	\$28,019	\$29,646	\$28,139	\$29,876	\$28,330
Net Impact	-\$9,498	-\$1,348	\$26,005	\$27,545	\$60,278	\$27,708	\$26,255	\$27,882	\$26,375	\$28,112	\$26,566
The 11-year NPV of Impact is \$179,187.											

Appendix J

Proposed Rule Text

15A NCAC 13A .0111 is proposed for amendment as follows:

15A NCAC 13A .0111 STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES - PART 266

(a) 40 CFR 266.20 through 266.23 (Subpart C), "Recyclable Materials Used in a Manner Constituting Disposal" are incorporated by reference including subsequent amendments and editions.

(b) 40 CFR 266.70 (Subpart F), "Recyclable Materials Utilized for Precious Metal Recovery" is incorporated by reference including subsequent amendments and editions. Off-site recycling facilities that receive materials described in 40 CFR 266.70(a) shall mark or label each container and tank holding recyclable materials at off-site precious metal recycling facilities with the words "Recyclable Material."

(c) 40 CFR 266.80 (Subpart G), "Spent Lead-Acid Batteries Being Reclaimed" is incorporated by reference including subsequent amendments and editions.

(d) 40 CFR 266.100 through 266.112 (Subpart H), "Hazardous Waste Burned in Boilers and Industrial Furnaces" are incorporated by reference including subsequent amendments and editions.

(e) 40 CFR 266.200 through 266.206 (Subpart M), "Military Munitions" are incorporated by reference including subsequent amendments and editions.

(f) 40 CFR 266.210 through 266.360 (Subpart N), "Conditional Exemption for Low-Level Mixed Waste Storage, Treatment, Transportation and Disposal" are incorporated by reference including subsequent amendments and editions.

(g) 40 CFR 266.500 through 266.510 (Subpart P), "Hazardous Waste Pharmaceuticals" are incorporated by reference including subsequent amendments and editions.

(g)(h) Appendices to 40 CFR Part 266 are incorporated by reference including subsequent amendments and editions.

*History Note: Authority G.S. 130A-294(c);
Eff. July 1, 1985;
Amended Eff. June 1, 1990; June 1, 1988; February 1, 1988; December 1, 1987;
Transferred and Recodified from 10 NCAC 10F .0039 Eff. April 4, 1990;
Recodified from 15A NCAC 13A .0012 Eff. August 30, 1990;
Amended Eff. January 1, 1995; April 1, 1993; August 1, 1991; October 1, 1990;
Recodified from 15A NCAC 13A .0011 Eff. December 20, 1996;
Amended Eff. April 1, 2006; April 1, 2003; April 1, 1999; August 1, 1998;
Temporary Amendment Eff. May 30, 2017 (replaced by the rule effective March 1, 2018);
Readopted Eff. March 1, 2018.;
Amended Eff. July 1, 2020.*